

## EUROPEAN DECLARATION OF CONFORMITY <sup>1</sup>

Declaration confirms that the product listed below meets: Regulations 2017/745 and is issued under the sole responsibility of Smith & Nephew Medical Limited <sup>2</sup>.

<b>Manufacturer's Name<sup>3</sup></b>	Smith & Nephew Medical Limited
<b>Business Address<sup>4</sup></b>	101 Hessle Road Hull, HU3 2BN United Kingdom
<b>Single Registration Number (SRN) <sup>5</sup></b>	TBD
<b>European Authorised Representative<sup>6</sup></b>	Smith & Nephew Operations B.V.
<b>Business Address<sup>7</sup></b>	Bolemlaan 2, 2132 NP Hoofddorp, Netherlands
<b>Product Name<sup>8</sup>:</b>	RENASYS Y-Connector
<b>Intended Use<sup>9</sup></b>	RENASYS TOUCH is indicated for patients who would benefit from a suction device (Negative Pressure Wound Therapy) as it may promote wound healing via removal of fluids, including irrigation and body fluids, wound exudates and infectious materials. The following wound types may be used with a RENASYS system that is utilizing a RENASYS Y-connector: <ul style="list-style-type: none"> <li>• Flaps and grafts (only in one wound configuration)</li> <li>• Open abdomen (only in one wound configuration &amp; only with RENASYS TOUCH and RENASYS AB Abdominal Kit)</li> <li>• Chronic</li> <li>• Acute</li> <li>• Traumatic</li> <li>• Sub-Acute and dehisced wounds</li> <li>• Ulcers (such as pressure or diabetic)</li> <li>• Partial-thickness burns</li> </ul>
<b>Conformity Assessment Procedure (Annex)<sup>10</sup></b>	Not applicable
<b>Notified Body Name<sup>11</sup></b>	Not applicable
<b>Notified Body Number<sup>12</sup></b>	Not applicable
<b>Verification Certificate(s)<sup>13</sup></b>	Not applicable

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Registered No. 605496 in England and Wales, registered Office: PO Box 81, 101 Hessle Road, Hull, HU3 2BN, England  
 Smith & Nephew Medical Limited, acting as agent for T.J. Smith and Nephew, Limited.

Signed on behalf of Legal Manufacturer Name <sup>14</sup>	
Signature <sup>15</sup>	
Name <sup>16</sup>	STEEVE LAMYONEE
Position <sup>17</sup>	RA DIRECTOR
Date <sup>18</sup>	21-MAY-2021
Location <sup>19</sup>	HULL, UK
Declaration of Conformity Reference <sup>20</sup>	DOC-WMTF-011/V1

Product Schedule <sup>21</sup>			
Product Code / Catalogue Number <sup>22</sup>	Product Description or Product Variant <sup>23</sup>	Risk Classification <sup>24</sup>	Basic UDI <sup>25</sup>
66800971	RENASYS Y-Connector	Class I	5000223SN000101QT

Standards / Common Specification(s) <sup>26</sup> :		
EN ISO 780: 2015	EN ISO 14971:2012	EN ISO 10993-10: 2010
EN ISO 13485: 2016	ISO 10993-1:2018	EN 1041: 2008+A1:2013
EN ISO 15223-1: 2016	EN ISO 10993-5:2009	EN 62366-1: 2015

**Intended Use European Language Translations<sup>27</sup>:**

Language <sup>28</sup>		Code	Intended Use
EN	Local		
Bulgarian	български език	BG	<p>RENASYS TOUCH е показана за пациенти, които биха имали полза от аспирационно изделие (терапия за рани с отрицателно налягане), тъй като то може да допринесе за зарастването на рани чрез отстраняването на течности, включително иригационни и телесни течности, раневи ексудати и инфекциозни материали. Система RENASYS, използваща Y-конектор RENASYS може да се използва при следните видове рани:</p> <ul style="list-style-type: none"> <li>• Ламба и присадки (само в конфигурация с една рана)</li> <li>• Отворени коремни рани (само в конфигурация с</li> </ul>

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			<p>една рана и само с RENASYS TOUCH и абдоминален кит RENASYS AB)</p> <ul style="list-style-type: none"> <li>• Хронични</li> <li>• Остри</li> <li>• Травматични</li> <li>• Субакутни и дехисцентни рани</li> <li>• Язви (като от натиск или диабетни)</li> <li>• Изгаряния с частична дебелина</li> </ul>
Croatian	Hrvatski	HR	<p>RENASYS TOUCH indiciran je za pacijente koji bi imali koristi od liječenja rane usisnim proizvodom (terapija rane negativnim tlakom) jer može potaknuti zacjeljivanje rana uklanjanjem tekućina, uključujući tekućine za ispiranje i tjelesne tekućine, eksudata rane i infektivnih materijala.</p> <p>Sljedeće vrste rana prikladne su za uporabu sustava RENASYS s Y-priključkom RENASYS:</p> <ul style="list-style-type: none"> <li>• režnjevi i graftovi (samo u konfiguraciji jedne rane)</li> <li>• otvoreni abdomen (samo u konfiguraciji jedne rane i samo s RENASYS TOUCH i abdominalnim kompletom RENASYS AB)</li> <li>• kronične</li> <li>• akutne</li> <li>• traumatske</li> <li>• subakutne i dehiscentne rane</li> <li>• ulcerozne (kao što su one uzrokovane tlakom ili dijabetesom)</li> <li>• opekline drugog stupnja.</li> </ul>
Czech	Český Jazyk	CZ	<p>Systém RENASYS TOUCH je určen pro pacienty, kteří by mohli mít užitek z odsávacího zařízení (podtlaková léčba ran neboli Negative Pressure Wound Therapy), protože to může urychlit hojení rány díky odstranění tekutin, včetně irigace a tělních tekutin, exsudátu z rány a infekčního materiálu.</p> <p>Systém RENASYS s využitím Y-konektoru lze použít u následujících typů ran:</p> <ul style="list-style-type: none"> <li>• laloky a štěpy (pouze při konfiguraci pro jednu ránu)</li> <li>• otevřené břicho (pouze u konfigurace pro jednu ránu a pouze se systémem RENASYS TOUCH a sadou RENASYS AB Abdominal Kit)</li> <li>• chronické</li> <li>• akutní</li> <li>• traumatické</li> <li>• subakutní rány a rány s dehiscencí</li> <li>• ulcerující (např. dekubity nebo diabetické rány)</li> <li>• popáleniny druhého stupně</li> </ul>
Danish	Dansk	DK	<p>RENASYS TOUCH er indiceret til patienter, som vil have gavn af en sugepumpe (sårbehandling med negativt tryk), da den kan fremme sårhelingen ved at fjerne væsker, herunder skylle- og kropsvæsker, sårsekssudater og infektiøst materiale.</p> <p>Et RENASYS-system, der bruger en RENASYS Y-</p>

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			<p>konnektor, kan anvendes til følgende sårtyper:</p> <ul style="list-style-type: none"> <li>• Lapper og grafts (kun i en konfiguration med ét sår)</li> <li>• Åbne abdominale (kun i en konfiguration med ét sår og kun med RENASYS TOUCH og RENASYS AB abdominalsæt)</li> <li>• Kroniske</li> <li>• Akutte</li> <li>• Traumatiske</li> <li>• Subakutte og rumperede sår</li> <li>• Sår i form af tryksår eller diabetiske sår</li> <li>• Delhudsforbrændinger</li> </ul>
Dutch	Nederlands	NL	<p>De RENASYS TOUCH is geïndiceerd voor patiënten die baat zouden hebben bij het gebruik van een afzuighulpmiddel (negatieve-druktherapie, NDT), omdat dit de wondgenezing kan bevorderen door verwijdering van vloeistoffen, inclusief irrigatie- en lichaamsvloeistoffen, wondexsudaat en infectieus materiaal.</p> <p>Bij volgende wondtypes mag een RENASYS-systeem met gebruik van een RENASYS Y-connector gebruikt worden:</p> <ul style="list-style-type: none"> <li>• Lappen en transplantaten (alleen bij configuratie voor één wond)</li> <li>• Open abdomen (alleen bij configuratie voor één wond &amp; alleen met RENASYS TOUCH en RENASYS AB abdominale kit)</li> <li>• Chronisch</li> <li>• Acuut</li> <li>• Traumatisch</li> <li>• Subacuut en wonden met dehiscentie</li> <li>• Zweren (zoals decubitus- of diabetische ulcera)</li> <li>• Tweedegraads brandwonden</li> </ul>
Estonian	Eesti	EE	<p>RENASYS TOUCH on mõeldud patsientidele, kes võivad saada abi vaakumseadmest (vaakumravist), mis võib kiirendada haava paranemist vedelike, näiteks loputusvee ja kehavedelike, haavaeritiste ja nakkuslike materjalide, eemaldamise teel.</p> <p>Süsteemi RENASYS ja koos sellega RENASYS-i Y-liitmikku saab kasutada järgmiste haavaliikide korral:</p> <ul style="list-style-type: none"> <li>• nahalapid ja -siirikud (ainult ühe haava konfiguratsioonis)</li> <li>• avatud kõht (ainult ühe haava konfiguratsioonis ning ainult koos süsteemiga RENASYS TOUCH ja kõhukomplektiga RENASYS AB)</li> <li>• kroonilised</li> <li>• ägedad</li> <li>• traumaatilised</li> <li>• alaägedad ja irevil haavad</li> <li>• haavandid (näiteks lamatishaavandid või diabeetilised haavandid)</li> <li>• II astme põletused</li> </ul>
Finnish	Suomi	FI	RENASYS TOUCH -järjestelmä on tarkoitettu

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			<p>käytettäväksi potilailla, jotka hyötyvät imulaitteen (alipainetta hyödyntävän haavanhoitojärjestelmän) käytöstä, sillä se voi edistää haavan paranemista poistamalla nesteitä, kuten huuhtelu- ja kehon nesteitä, tulehdusnesteitä ja infektiota aiheuttavia aineita.</p> <p>RENASYS Y-yhdistäjää hyödyntävän RENASYS-järjestelmän kanssa voidaan käyttää seuraavia haavatyyppejä:</p> <ul style="list-style-type: none"> <li>• ihokielekkeet ja ihonsiirteet (vain yhden haavan hoidossa)</li> <li>• avoin vatsa (vain yhden haavan hoidossa ja vain RENASYS TOUCH:in ja RENASYS AB -vatsapakkauksen kanssa)</li> <li>• krooninen</li> <li>• akuutti</li> <li>• traumaattinen</li> <li>• subakuutit ja auenneet haavat</li> <li>• haavaumat (kuten paine- tai diabeettiset haavat)</li> <li>• toisen asteen palovammat</li> </ul>
French	Français	FR	<p>Le dispositif RENASYS TOUCH est indiqué chez les patients pouvant bénéficier d'un dispositif d'aspiration (traitement des plaies par pression négative), car il peut favoriser la cicatrisation de la plaie par aspiration des liquides, notamment les liquides corporels et d'irrigation, les exsudats de plaie et les matières infectieuses.</p> <p>Un système RENASYS équipé du connecteur en Y RENASYS peut être utilisé avec les types de plaies suivants :</p> <ul style="list-style-type: none"> <li>• lambeaux et greffes (uniquement en configuration à une seule plaie)</li> <li>• Abdomen ouvert (uniquement en configuration à une seule plaie et uniquement avec RENASYS TOUCH et le kit abdominal RENASYS AB)</li> <li>• Chroniques</li> <li>• Aiguës</li> <li>• Traumatiques</li> <li>• Plaies subaiguës et déhiscentes</li> <li>• Ulcères (comme les ulcères de pression ou diabétiques)</li> <li>• Brûlures au deuxième degré</li> </ul>
German	Deutsch	DE	<p>RENASYS TOUCH ist für Patienten indiziert, die von einer Absaugvorrichtung (Unterdruck-Wundtherapie) profitieren können, da diese die Wundheilung durch das Absaugen von Flüssigkeiten, einschließlich Spülflüssigkeiten und Körperflüssigkeiten, Wundexsudate und infektiöse Materialien, fördert.</p> <p>Das RENASYS-System mit RENASYS Y-Konnektor kann bei folgenden Wundtypen verwendet werden:</p> <ul style="list-style-type: none"> <li>• Lappenplastiken und Transplantationswunden (nur bei der Konfiguration mit einer Wunde)</li> <li>• Offenes Abdomen (nur bei Konfigurationen mit</li> </ul>

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			<p>einer Wunde und nur mit RENASYS TOUCH und RENASYS AB Abdominalkit)</p> <ul style="list-style-type: none"> <li>• Chronische Wunden</li> <li>• Akute Wunden</li> <li>• Traumatische Wunden</li> <li>• Subakute und dehiszente Wunden</li> <li>• Ulzera (z. B. Druck- oder diabetischer Ulzerus)</li> <li>• Verbrennungen zweiten Grades</li> </ul>
Greek	Ελληνικά	GR	<p>Το σύστημα RENASYS TOUCH ενδείκνυται για ασθενείς που θα ωφελούνταν από μια συσκευή αναρρόφησης (θεραπεία τραύματος με αρνητική πίεση), καθώς μπορεί να συμβάλει στην επούλωση του τραύματος μέσω απομάκρυνσης των υγρών, συμπεριλαμβανομένων των υγρών καταιονισμού και των σωματικών υγρών, των εξιδρωμάτων του τραύματος και των μολυσματικών υλικών.</p> <p>Για τους παρακάτω τύπους τραυμάτων ενδείκνυται η χρήση ενός συστήματος RENASYS, το οποίο χρησιμοποιεί έναν σύνδεσμο σχήματος Y RENASYS:</p> <ul style="list-style-type: none"> <li>• Κρημνοί και μοσχεύματα (μόνο με τη διαμόρφωση ενός τραύματος)</li> <li>• Ανοικτή κοιλιακή χώρα (μόνο με τη διαμόρφωση ενός τραύματος και μόνο με το RENASYS TOUCH και το κιτ κοιλιακής χώρας RENASYS AB)</li> <li>• Χρόνια τραύματα</li> <li>• Οξεία τραύματα</li> <li>• Τραύματα κακώσεων</li> <li>• Υποξεία τραύματα και τραύματα που έχουν διαρρηχθεί</li> <li>• Έλκη (όπως οι κατακλίσεις ή τα διαβητικά έλκη)</li> <li>• Εγκαύματα μερικού πάχους</li> </ul>
Hungarian	Magyar	HU	<p>A RENASYS TOUCH rendszer olyan betegekhez javallt, akiknél a szívdésköz (negatív nyomású sebkezelés) előnyös lehet, mert elősegíti a seb gyógyulását a folyadékok – köztük az irrigációs folyadékok és a testfolyadékok –, valamint a sebváladékok és a fertőző anyagok eltávolítása révén.</p> <p>A következő sebtípusokhoz megfelelő a RENASYS Y-csatlakozót használó RENASYS rendszer:</p> <ul style="list-style-type: none"> <li>• lebenyek és graftok (csak egysebes konfigurációban)</li> <li>• nyílt hasi seb (csak egysebes konfigurációban és csak RENASYS TOUCH és RENASYS AB hasi készlettel)</li> <li>• krónikus</li> <li>• akut</li> <li>• traumás</li> <li>• szubakut és szétnyílt sebek</li> <li>• fekélyek (pl. nyomásos vagy diabetikus)</li> <li>• részleges mélységű égési sérülések</li> </ul>
Italian	Italiano	IT	<p>RENASYS TOUCH è indicato per i pazienti che trarrebbero beneficio da un dispositivo di aspirazione (terapia a pressione negativa per il</p>

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			<p>trattamento delle ferite), in quanto può favorire la guarigione della ferita attraverso la rimozione dei liquidi, compresi liquidi corporei e per irrigazione, essudati delle ferite e materiali infettivi.</p> <p>I seguenti tipi di ferite sono compatibili con sistemi RENASYS che utilizzano un connettore a Y RENASYS:</p> <ul style="list-style-type: none"> <li>• Lembi e innesti (solo nella configurazione per una ferita)</li> <li>• Addome aperto (solo nella configurazione per una ferita e solo con RENASYS TOUCH e kit addominali RENASYS AB)</li> <li>• Ferite croniche</li> <li>• Ferite acute</li> <li>• Ferite traumatiche</li> <li>• Ferite subacute e deiscenti</li> <li>• Ulcere (come quelle da pressione o diabetiche)</li> <li>• Ustioni a spessore parziale</li> </ul>
Latvian	Latviešu	LV	<p>RENASYS TOUCH ir indicēts pacientiem, kuri gūst labumu no atsūkšanas ierīces (negatīva spiediena brūču terapija), jo tā var veicināt brūču sadzīšanu, izvadot šķidrumus, iekļaujot skalošanas un ķermeņa šķidrumus, brūču eksudātu un infekciozus materiālus.</p> <p>RENASYS sistēmu, ar kuru izmanto RENASYS Y veida savienotāju, var izmantot šādiem brūču veidiem:</p> <ul style="list-style-type: none"> <li>• lēveri un transplantāti (tikai vienas brūces konfigurācijā);</li> <li>• atvērta vēdera (tikai vienas brūces konfigurācijā un tikai ar RENASYS TOUCH un RENASYS AB vēdera dobuma komplektu);</li> <li>• hroniskas;</li> <li>• akūtas;</li> <li>• traumatiskas;</li> <li>• subakūtas un plēstas brūces;</li> <li>• čūlas (spiediena vai diabēta);</li> <li>• daļēja biezuma apdegumi.</li> </ul>
Lithuanian	Lietuvių	LT	<p>RENASYS TOUCH skirta pacientams, kuriems būtų naudinga naudoti siurbimo prietaisą (neigiamo slėgio žaizdų terapija), nes dėl skysčių, įskaitant plovimo ir kūno skysčių, žaizdos eksudatų ir infekcinių medžiagų, pašalinimo tai gali skatinti žaizdą gyti.</p> <p>RENASYS sistemą ir RENASYS Y formos jungtį galima naudoti toliau išvardytų tipų žaizdoms:</p> <ul style="list-style-type: none"> <li>• lopa ir transplantatai (tik vienos žaizdos konfiguracija);</li> <li>• atvirosios pilvo (tik vienos žaizdos konfiguracija ir tik su RENASYS TOUCH ir RENASYS AB pilvo rinkinių);</li> <li>• lėtinės;</li> <li>• ūmios;</li> <li>• trauminės;</li> </ul>

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			<ul style="list-style-type: none"> <li>• apyūmēs arba žiojėjančios;</li> <li>• opos (sukeltos nuogulų ar diabeto);</li> <li>• dalinio storio nudegimai.</li> </ul>
Polish	Polski	PL	<p>System RENASYS TOUCH jest wskazany do stosowania u pacjentów, którzy mogą odnieść korzyść z urzą dzenia odsysającego (podciś nieniowe leczenia ran), ponieważ system moż e sprzyjać gojeniu się ran poprzez usuwanie płynów, w tym płynów irygacyjnych i płynów ustrojowych, wysię ków z rany i materiałów zakaź nych. Nastę pują ce typy ran mogą być leczone przy uż yciu system RENASYS wykorzystują cego złą cze Y RENASYS:</p> <ul style="list-style-type: none"> <li>• Płaty i przeszczepy (wyłą cznie w konfiguracji jednej rany)</li> <li>• Otwarta jama brzuszna (wyłą cznie w konfiguracji jednej rany i wyłą cznie z RENASYS TOUCH i zestawem brzuszny RENASYS AB)</li> <li>• Rany przewlekłe,</li> <li>• Rany ostre,</li> <li>• Rany urazowe,</li> <li>• Rany podostre i z rozchodzą cymi się brzegami,</li> <li>• Owrzodzenia (np. cukrzycowe lub odleż yny),</li> <li>• Oparzenia z czę ś ciovymi ranami głę bszymi,</li> </ul>
Portuguese	Português	PT	<p>O RENASYS TOUCH é indicado para pacientes que possam beneficiar de um dispositivo de sucção (terapia de feridas por pressão negativa), uma vez que pode promover a cicatrização de feridas através da remoção de fluidos, incluindo fluidos de irrigação e fluidos corporais, exsudados de feridas e materiais infecciosos.</p> <p>Os seguintes tipos de ferida podem ser utilizados com o Sistema RENASYS que utiliza um conector Y RENASYS:</p> <ul style="list-style-type: none"> <li>• Retalhos e enxertos (apenas configuração de uma ferida)</li> <li>• Abdómen aberto (apenas configuração de uma ferida e apenas com o RENASYS TOUCH e o kit abdominal RENASYS AB)</li> <li>• Crónica</li> <li>• Aguda</li> <li>• Traumática</li> <li>• Feridas subagudas e deiscentes</li> <li>• Úlceras (como diabéticas ou de pressão)</li> <li>• Queimaduras de espessura parcial</li> </ul>
Romanian	Română	RO	<p>RENASYS TOUCH este indicat pentru pacienții care ar beneficia de pe urma utilizării unui dispozitiv de aspirație (terapie cu presiune negativă a plăgii) deoarece aceasta ar putea susține vindecarea plăgii prin îndepărtarea fluidelor, inclusiv a fluidelor de irigare și a celor corporale, a exsudatului plăgii și a materialelor infecțioase.</p>

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			<p>Următoarele tipuri de plăgi pot beneficia de folosirea sistemului RENASYS cu utilizarea unui conector în Y RENASYS:</p> <ul style="list-style-type: none"> <li>• Lambouri și grefe (doar în configurație cu o singură plagă)</li> <li>• Abdomen deschis (doar în configurație cu o singură plagă și doar cu RENASYS TOUCH și trusa abdominală RENASYS AB)</li> <li>• Cronice</li> <li>• Acute</li> <li>• Traumatische</li> <li>• Plăgi subacute și dehiscente</li> <li>• Ulcere (cum ar fi cele de decubit sau diabetice)</li> <li>• Arsuri de grosime parțială</li> </ul>
Slovak	Slovenčina	SK	<p>RENASYS TOUCH je indikovaný u pacientov, ktorí môžu mať úžitok z odsávacieho zariadenia (liečba rany s podtlakom), pretože to môže podporiť liečbu rany prostredníctvom odsávania tekutín, vrátane irigačných a telesných tekutín, výpotkov z rán a infekčných materiálov.</p> <p>Systém RENASYS, ktorý používa konektor RENASYS v tvare Y možno použiť na tieto typy rán:</p> <ul style="list-style-type: none"> <li>• neštepené transplantáty a štepy (iba v konfigurácii jednou ranou)</li> <li>• otvorené abdominálne (iba v konfigurácii s jednou ranou a s RENASYS TOUCH a abdominálnou súpravou RENASYS AB)</li> <li>• chronické</li> <li>• akútne</li> <li>• úrazové</li> <li>• subakútne a dehiscentné rany</li> <li>• vrede (ako napr. tlakové alebo diabetické)</li> <li>• popáleniny čiastočnej hrúbky</li> </ul>
Slovenian	Slovenščina	SI	<p>RENASYS TOUCH je indiciran za paciente, katerim bi sesalni pripomoček (zdravljenje rane z negativnim tlakom) koristil, saj lahko pospeši celjenje rane z odstranitvijo tekočin, vključno z izpiralnimi in telesnimi tekočinami, izcedki iz rane in kužnimi materiali.</p> <p>Sistem RENASYS, ki uporablja Y-konektor RENASYS, se lahko uporablja pri naslednjih vrstah ran:</p> <ul style="list-style-type: none"> <li>• zakrilca in grafti (samo pri konfiguraciji ene rane);</li> <li>• odprte trebušne rane (samo pri konfiguraciji ene rane in samo s sistemom RENASYS TOUCH in abdominalnim kompletom RENASYS AB);</li> <li>• kronične;</li> <li>• akutne;</li> <li>• poškodbene;</li> <li>• subakutne in razprte rane;</li> <li>• razjede (npr. preležaninske ali diabetične);</li> <li>• opekline druge stopnje.</li> </ul>
Spanish	Español	ES	RENASYS TOUCH está indicado para pacientes que

This document has been compiled in accordance with SOP ref. 2014016.

			<p>pueden beneficiarse de un dispositivo de aspiración (terapia de heridas de presión negativa), ya que puede favorecer la cicatrización de las heridas mediante la retirada de líquidos, incluidos los líquidos corporales y de irrigación, los exudados de las heridas y los materiales infecciosos.</p> <p>Los tipos de heridas siguientes pueden utilizarse con un Sistema RENASYS que incluya un conector en Y RENASYS:</p> <ul style="list-style-type: none"> <li>• Colgajos e injertos (solo en configuración de una herida)</li> <li>• Abdomen abierto (solo en configuración de una herida y solo con el RENASYS TOUCH y el kit abdominal RENASYS AB)</li> <li>• Crónica</li> <li>• Aguda</li> <li>• Traumática</li> <li>• Heridas subagudas y con dehiscencia</li> <li>• Úlceras (como las úlceras por presión o las diabéticas)</li> <li>• Quemaduras de espesor parcial</li> </ul>
Swedish	Svenska	SE	<p>RENASYS TOUCH är indicerad för patienter som skulle gynnas av en sugenhet (sårbehandling med negativt tryck), då det kan främja sårhäkning genom att avlägsna vätskor, inklusive spolningsvätskor och kroppsvätskor, sårexsudat och infektiösa material.</p> <p>Ett RENASYS-system som använder en RENASYS Y-koppling kan användas på följande sårtyper:</p> <ul style="list-style-type: none"> <li>• lambåer och grafter (endast för konfigurering av ett sår)</li> <li>• öppna abdominalsår (endast för konfigurering av ett sår &amp; endast med with RENASYS TOUCH och RENASYS AB abdominalkit)</li> <li>• kroniska</li> <li>• akuta</li> <li>• traumatiska</li> <li>• subakuta och rupturerade sår</li> <li>• diabetessår och trycksår</li> <li>• delhudsbrännskador</li> </ul>

## Appendices - European Language Term Translations:

Appendix no.	Language (EN)	Language (Local)	Country Code
Appendix 1	Bulgarian	български език	BG
Appendix 2	Croatian	Hrvatski	HR
Appendix 3	Czech	Český Jazyk	CZ

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Appendix 4	Danish	Dansk	DK
Appendix 5	Dutch	Nederlands	NL
Appendix 6	Estonian	Eesti	EE
Appendix 7	Finnish	Suomi	FI
Appendix 8	French	Français	FR
Appendix 9	German	Deutsch	DE
Appendix 10	Greek	Ελληνικά	GR
Appendix 11	Hungarian	Magyar	HU
Appendix 12	Italian	Italiano	IT
Appendix 13	Latvian	Latviešu	LV
Appendix 14	Lithuanian	Lietuvių	LT
Appendix 15	Polish	Polski	PL
Appendix 16	Portuguese	Português	PT
Appendix 17	Romanian	Română	RO
Appendix 18	Slovak	Slovenčina	SK
Appendix 19	Slovenian	Slovenščina	SL
Appendix 20	Spanish	Español	ES
Appendix 21	Swedish	Svenska	SE

This document has been compiled in accordance with SOP ref. 2014016.

Registered No. 605496 in England and Wales, registered Office: PO Box 81, 101 Hessle Road, Hull, HU3 2BN, England  
Smith & Nephew Medical Limited, acting as agent for T.J. Smith and Nephew, Limited.

# EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

## MDR 732832 R000

**Manufacturer:** Smith & Nephew Medical Ltd

**Address:**

101 Hessle Road  
Hull  
HU3 2BN  
United Kingdom

**Single Registration Number:** GB-MF-000017580

**EU Authorised Representative:** Smith & Nephew Operations B.V.

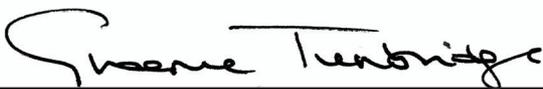
**Address:**

Bloemlaan 2  
2132 NP Hoofddorp  
Netherlands

**Scope:** See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):



Graeme Tunbridge, Senior Vice President Medical Devices

First Issue Date: **2021-09-07**

Current Issue Date: **2023-06-05**

Starting Validity Date: **2023-06-05**

Expiry Date: **2026-09-06**

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# EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

## MDR 732832 R000

### Device Schedule: Class III and Class IIb devices

Class III	Intended purpose
BIOBRANE porcine gelatin wound dressings and gloves	See MDR 733300
Durafiber Ag	See MDR 737177
ALLEVYN Ag Adhesive	See MDR 737178
ALLEVYN Ag Non-adhesive	See MDR 737179
ALLEVYN Ag Gentle Border	See MDR 737180
Class IIb	Intended purpose
Foam Wound Dressings with Silicone Adhesive (with and without border)	Wound management on shallow, granulating wounds, chronic and acute exudative wounds, full and partial thickness wounds. Can also be used for pressure ulcer prevention (bordered version).
Alginate wound dressings	To treat pressure sores and venous leg ulcers, with moderate to heavy exudate. To facilitate the control of minor bleeding.
Hydrogel dressings	For the removal of non-viable tissue from shallow, undermined and deep wounds (e.g. pressure ulcers, leg ulcers, diabetic foot ulcers, burns, open surgical wounds, scalds, lacerations, grazes, and malignant and fungating wounds). Also, for the treatment of granulating cavity wounds and radiation damage.
Superabsorbent Wound Dressings with Silicone Adhesive (with and without border)	Wound management by secondary intention on shallow, granulating wounds, chronic and acute exudative wounds, full and partial thickness wounds (e.g. pressure ulcers, leg ulcers, diabetic foot ulcers, surgical wounds, first and second degree burns, donor sites, skin tears, and fungating ulcers) Can also be used for pressure ulcer prevention (bordered version).

First Issue Date: **2021-09-07**

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# EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

## MDR 732832 R000

Class IIb	Intended purpose
Gauze impregnated without antiseptic	To treat wounds such as minor burns and scalds, donor and recipient graft sites, skin loss wounds, lacerations, abrasions and chronic wounds (e.g. leg ulcers, pressure sores).
Hydrocellular Foam Wound Dressings (with and without border)	For wound management by secondary intention on shallow, granulating wounds chronic and acute exudative wounds, full and partial thickness wounds (e.g. pressure ulcers, leg ulcers, diabetic foot ulcers, malignant wounds, surgical wounds, donor sites, and fungating ulcers).
Polyurethane dressings	Management of superficial wounds with light exudate (e.g. minor burns and abrasions, pressure ulcers, leg ulcers, surgical wounds, skin graft donor sites), apart from dressing 15cm x 15cm which is intended for the treatment of pressure ulcers and venous leg ulcers that heal by secondary intention with light exudate.
Non-adhesive absorbent dressings	<p>Primary dressing for exudate absorption and the management of superficial to full thickness wounds (e.g. first and second degree burns, venous leg ulcers, and skin grafts, including those treated with Bio-engineered skin substitutes).</p> <p>May also be used for:</p> <ul style="list-style-type: none"> <li>- exudate management associated with Lymphedema</li> <li>- exudate management and anti-shear benefits associated with Skin Sloughing Disorders</li> <li>- exudate management associated with superficial to full thickness wounds treated with Bio-engineered skin substitutes.</li> </ul>

First Issue Date: **2021-09-07**

Current Issue Date: **2023-06-05**

Starting Validity Date: **2023-06-05**

Expiry Date: **2026-09-06**

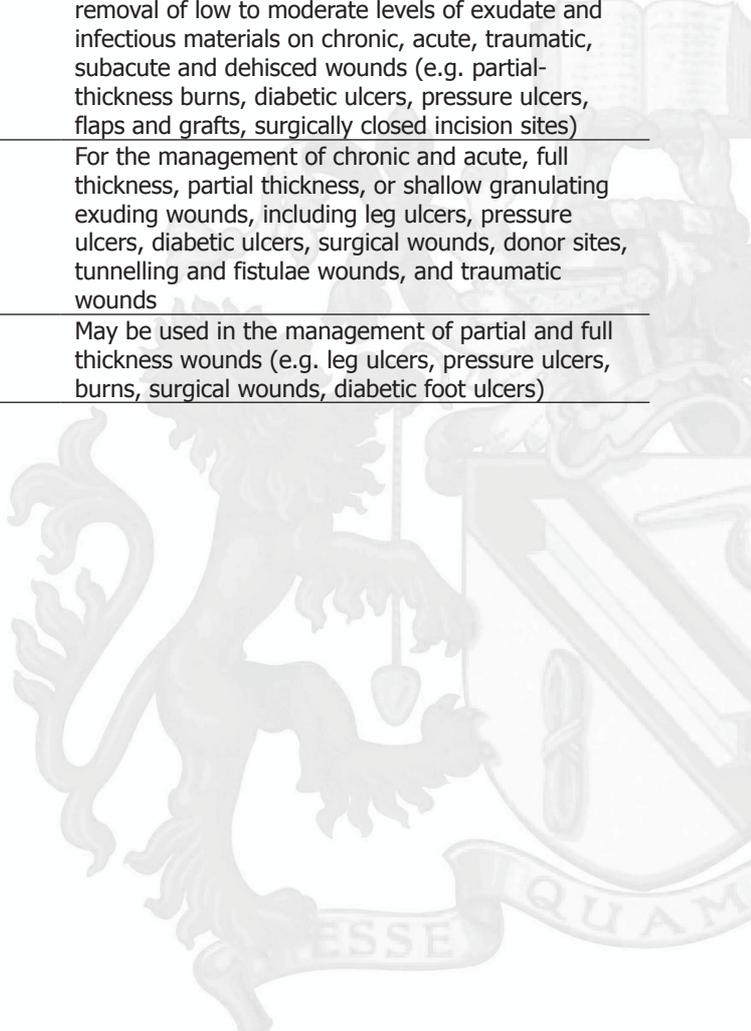
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# EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

## MDR 732832 R000

Class IIb	Intended purpose
Single Use Negative Pressure Wound Therapy System	For patients who would benefit from a suction device (NPWT) as it may promote wound healing via removal of low to moderate levels of exudate and infectious materials on chronic, acute, traumatic, subacute and dehisced wounds (e.g. partial-thickness burns, diabetic ulcers, pressure ulcers, flaps and grafts, surgically closed incision sites)
Cellulose and / or Modified Cellulose Dressings	For the management of chronic and acute, full thickness, partial thickness, or shallow granulating exuding wounds, including leg ulcers, pressure ulcers, diabetic ulcers, surgical wounds, donor sites, tunnelling and fistulae wounds, and traumatic wounds
Wound Contact Layer Dressings	May be used in the management of partial and full thickness wounds (e.g. leg ulcers, pressure ulcers, burns, surgical wounds, diabetic foot ulcers)



First Issue Date: **2021-09-07**

Current Issue Date: **2023-06-05**

Starting Validity Date: **2023-06-05**

Expiry Date: **2026-09-06**

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# EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

## MDR 732832 R000

### Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from [Certificate.Verification@bsigroup.com](mailto:Certificate.Verification@bsigroup.com))

Date	Reference Number	Action
2021-09-07	3258304	Issued.
2022-01-13	3604563	Supplemented – Addition of device category Alginate wound dressings. Supplemented – Addition of device category Hydrogel dressings. Amended – Addition of legal manufacturer SRN. Amended - Addition of crucial supplier. Amended - Addition of critical subcontractor for sterilisation. Amended – Addition of 'Moist Heat Sterilisation' to the services provided by existing critical subcontractor.
2022-10-26	3658465	Amended – Correction of 'Class III Implantable' to 'Class III' in the scope table for Biobrane. Amended – Correction of Foam Wound Dressings with Silicone Adhesive to separate lines including 'with border' and 'without border'. Supplemented – Addition of Superabsorbent Wound Dressings with Silicone Adhesive devices (with border). Supplemented – Addition of Superabsorbent Wound Dressings with Silicone Adhesive devices (without border). Supplemented – Addition of Gauze impregnated without antiseptic devices. Amended – Addition of critical subcontractors for sterilisation.
2022-11-04	3772415	Supplemented – Addition of Durafiber Ag. Amended – Administrative update to the history.

First Issue Date: **2021-09-07**

Current Issue Date: **2023-06-05**

Starting Validity Date: **2023-06-05**

Expiry Date: **2026-09-06**

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# EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

## MDR 732832 R000

Date	Reference Number	Action
2023-01-05	3809641	Supplemented – Addition of Hydrocellular Foam Wound Dressings (with and without border). Supplemented – Addition of Polyurethane dressings. Supplemented – Addition of Non-adhesive absorbent dressings. Amended – Correction of wording for Foam Wound Dressings with Silicone Adhesive (with and without border) and Superabsorbent Wound Dressings with Silicone Adhesive (with and without border). Amended – Correction of date format to be as follow: YYYY-MM-DD.
2023-03-30	3768728	Supplemented – Addition of ALLEVYN Ag Adhesive Supplemented – Addition of ALLEVYN Ag Non-adhesive Supplemented – Addition of ALLEVYN Ag Gentle Border Supplemented – Addition of Single Use Negative Pressure Wound Therapy System
Current	30000467	Supplemented – Addition of Cellulose and / or Modified Cellulose Dressings Supplemented – Addition of Wound Contact Layer Dressings Amended – Addition of crucial supplier

First Issue Date: **2021-09-07**

Current Issue Date: **2023-06-05**

Starting Validity Date: **2023-06-05**

Expiry Date: **2026-09-06**

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# EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

**No.** CE 00356  
**Issued To:** **Smith & Nephew Medical Ltd**  
**101 Hessle Road**  
**Hull**  
**HU3 2BN**  
**United Kingdom**

In respect of:

**See certificate scope page.**

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):



Gary E Slack, Senior Vice President - Medical Devices

First Issued: **1994-12-05**

Date: **2020-01-31**

Expiry Date: **2024-05-26**

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Page 1 of 8

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

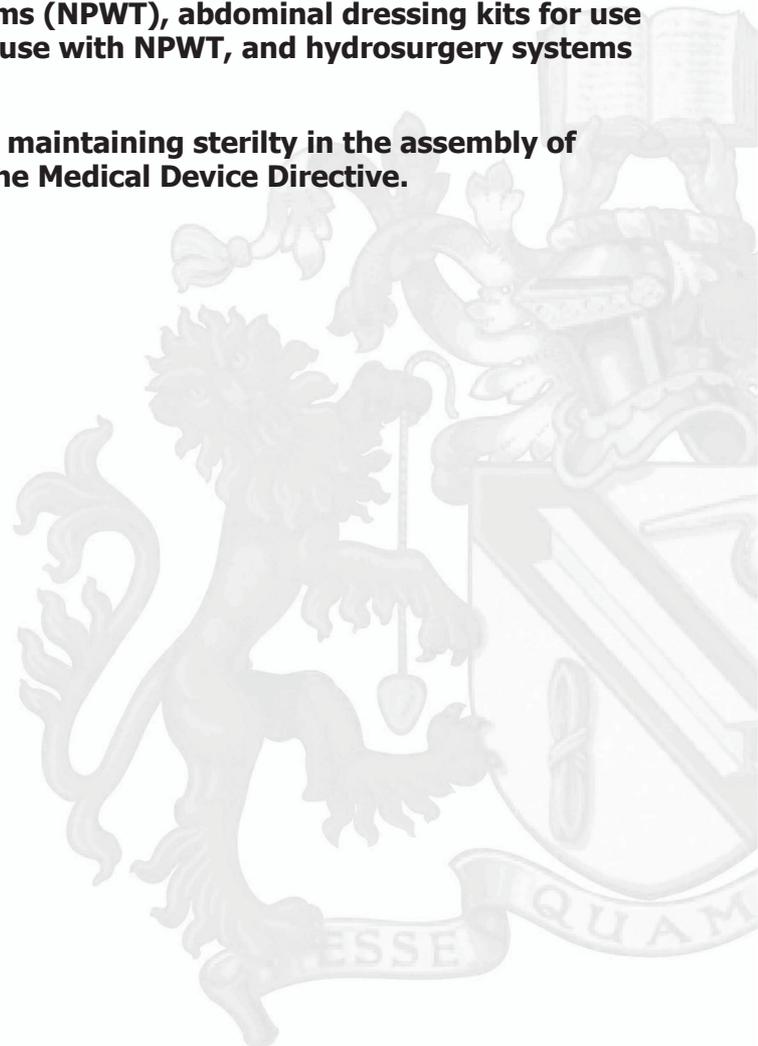
This certificate was issued electronically and is bound by the conditions of the contract.

Certificate No: CE 00356

## Certificate Scope:

**The design and manufacture of sterile or non-sterile wound management products in the following categories: wound dressings (see supplementary page), medicated wound dressings, wound dressings utilising animal derived materials (porcine gelatin), medicated bandages, medicated bandages utilising animal derived materials (porcine gelatine), cavity wound dressings, wound preparations, wound monitoring devices, multi-layer bandage systems, Negative Pressure Wound Therapy Systems (NPWT), abdominal dressing kits for use with NPWT, drain kits and drain accessory kits for use with NPWT, and hydrosurgery systems for wound debridement.**

**Those aspects of Annex II relating to securing and maintaining sterility in the assembly of procedure packs in accordance with Article 12 of the Medical Device Directive.**

First Issued: **1994-12-05**Date: **2020-01-31**Expiry Date: **2024-05-26**

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Page 2 of 8

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This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

# EC Certificate - Full Quality Assurance System

## Supplementary Information to CE 00356

Issued To: **Smith & Nephew Medical Ltd**  
**101 Hessle Road**  
**Hull**  
**HU3 2BN**  
**United Kingdom**

Number	Device Name	Intended Use per IFU
<b>Class III</b>		
MD 0301 MDS 7001 MDS 7006	Antimicrobial wound dressings	Refer to Design Examination certificates: CE 01105 CE 01409 CE 01714 CE 511078 CE 518880 CE 521887 CE 544419 CE 547893 CE 568730 CE 90692 CE 96076
MD 0301 MDS 7002 MDS 7006	Wound dressings containing porcine gelatine	Refer to Design Examination certificates: CE 01714 CE 650269

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Date: **2020-01-31**

Expiry Date: **2024-05-26**

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Page 3 of 8

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**Hull**  
**HU3 2BN**  
**United Kingdom**

Number	Device Name	Intended Use per IFU
<b>Class IIb</b>		
MD 0301	Foam wound dressings	Wound management by secondary intention on chronic and acute; full thickness, partial thickness or shallow; granulating, exuding wounds. Can also be used for pressure ulcer prevention
MD 0301	Hydrogel wound dressings	Management of shallow and deep open wounds healing by secondary intent
MD 0301	Odour absorbing non-woven wound dressings	For use on malodorous, partial to full thickness wounds and as a secondary dressing for superficial to full thickness wounds
MD 0303	Wound preparation devices	For the improvement/management of the wound environment to promote healing in acute and chronic wounds
MD 0301	Superabsorbent wound dressings	For the treatment and management of exuding wounds

First Issued: **1994-12-05**

Date: **2020-01-31**

Expiry Date: **2024-05-26**

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Page 4 of 8

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## Supplementary Information to CE 00356

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**Hull**  
**HU3 2BN**  
**United Kingdom**

Number	Device Name	Intended Use per IFU
MD 0301	Multi-layer bandage systems	For the management and treatment of venous leg ulcers and associated conditions
MD 0301	Alginate wound dressings	To treat pressure sores and venous leg ulcers, with moderate to heavy exudate. To facilitate the control of minor bleeding.
MD 0301	Gauze wound dressings	For the management of partial and full thickness wounds. For post-surgical covering over epithelial autograft sites and a means of stenting or anchoring skin substitutes. Can be used in conjunction with S&N Negative Pressure Wound Therapy (NPWT) systems
MD 1104	Hydrosurgery systems	Intended for wound debridement (acute, chronic wounds and burns), soft tissue debridement and cleansing of the surgical site

First Issued: **1994-12-05**

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Expiry Date: **2024-05-26**

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Page 5 of 8

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

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## Supplementary Information to CE 00356

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**Smith & Nephew Medical Ltd**  
**101 Hessle Road**  
**Hull**  
**HU3 2BN**  
**United Kingdom**

Number	Device Name	Intended Use per IFU
MD 0301	Cellulose based wound dressings	Wound management by secondary intention on chronic and acute; full thickness, partial thickness or shallow; granulating, exuding wounds
MD 0301	Hydrocolloid wound dressings	For use in the management of dry or lightly exuding wounds to moderately exuding wounds
MD 1103	Single use negative pressure wound therapy (NPWT) systems and associated dressing kits	For patients who would benefit from a suction device (negative pressure wound therapy) as it may promote wound healing via removal of low to moderate levels of exudates and infectious materials
MD 1103	Traditional negative pressure wound therapy (NPWT) systems and associated dressing kits	For patients who would benefit from a suction device (negative pressure wound therapy) as it may promote wound healing via removal of low to moderate levels of exudates and infectious materials

First Issued: **1994-12-05**

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Page 6 of 8

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

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**United Kingdom**

Number	Device Name	Intended Use per IFU
MD 0301	Abdominal dressing kits	Indicated for temporary bridging of abdominal wall openings where primary closure is not possible and / or repeat abdominal entries are necessary. It is intended to be used in open abdominal wounds with exposed viscera, including but not limited to abdominal compartment syndrome
MD 0303	Wound drainage kits	Intended to be used in conjunction with Smith & Nephew Negative Pressure Wound Therapy (NPWT) Systems

First Issued: **1994-12-05**

Date: **2020-01-31**

Expiry Date: **2024-05-26**

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Page 7 of 8

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**Hull**  
**HU3 2BN**  
**United Kingdom**

Number	Device Name	Intended Use per IFU
<b>Class IIa</b>		
MD 0302	Skin closure devices	--
MD 0301	Film wound dressings	--
MD 0301	Tulle Gras wound dressings	--
MD 0301	Foam wound dressings	--
MD 0301	Hydrogel wound dressings	--

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Expiry Date: **2024-05-26**

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# EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 00356**  
 Date: **2020-01-31**  
 Issued To: **Smith & Nephew Medical Ltd**  
**101 Hessele Road**  
**Hull**  
**HU3 2BN**  
**United Kingdom**

Date	Reference Number	Action
07 October 2004		Change of subcontractors activities from sterilization to control of sterilization.
24 June 2005		Change to scope, addition of supplementary information and addition of Nucryst Pharmaceuticals Corp. (Alberta), Steris Corporation Ismedix Services (Ontario) and Iotron Technologies Corp. (British Columbia) as subcontractors. Change of subcontractor name from "Smith & Nephew Fabrics" to "BSN Medical".
4 August 2005		Addition of 'Beam One LLC' as a subcontractor for E beam sterilization.
10 January 2006		Addition of Codan Steritex ApS as a subcontractor for Gamma Sterilization. Spelling correction to "Speciality" to read "Specialty" for Perstorp Specialty Chemicals AB.
30 January 2006		Addition of NAMSA (North American Science Associates, Inc) as a subcontractor for Microbiology Service.
16 March 2006		Addition of Derma Sciences, Inc as a subcontractor for Manufacture of Gauze dressings. Addition of Coloplast Corp as a subcontractor for Manufacture of Hydrocolloid dressings.

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Page 1 of 10

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This certificate was issued electronically and is bound by the conditions of the contract.

# EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 00356**  
 Date: **2020-01-31**  
 Issued To: **Smith & Nephew Medical Ltd**  
**101 Hesse Road**  
**Hull**  
**HU3 2BN**  
**United Kingdom**

Date	Reference Number	Action
26 April 2006		Addition to subcontractor activities for Derma Sciences, Inc and Coloplast Corp.
11 August 2006		Addition of Isotron plc (Reading) as a subcontractor for Gamma Sterilization.
07 December 2006		5 year certificate renewal and addition of Iotron Industries Canada, Inc. as a subcontractor for E Beam Sterilization.
01 March 2007		Amendment of Company Name from 'Smith & Nephew Wound Management' to 'Smith & Nephew Medical Ltd'. Removal of Beiersdorf AG from the list of significant subcontractors.
02 May 2007		Change of name of subcontractor Acordis Speciality Fibres to Speciality Fibres and Materials Ltd. Addition of Pharmaplast S.A.E. as a subcontractor for Manufacture, Control of Sterilization and ETO Sterilization.
24 October 2007		Addition of BeamOne LLC (both Denver and Lima sites) as significant subcontractors for E Beam Sterilisation.
06 July 2009	7392715	Addition of Smith & Nephew Medical (Suzhou) Limited as a subcontractor.

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Page 2 of 10

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Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

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Date	Reference Number	Action
29 April 2010	7506261	Extension to scope to include cellulose based gelling dressings. Subcontractor name change: Nucryst Pharmaceuticals Corp updated to Smith & Nephew (Alberta) Inc.
4 May 2011	7675089	Scope extension to include Negative Pressure Wound Therapy Systems. Addition of new subcontractors Avail Medical Products Inc., Texas, FLEXMedical Dallas, Texas and Sterigenics, Belgium.
13 July 2011	7715729	Addition of new subcontractor: Flextronics Technology (Shenzhen) Co. Ltd. for the activity of manufacture.
14 October 2011	7760098	Addition of new subcontractor KARL OTTO BRAUN GmbH & Co. KG, Germany for the activity of manufacture.
13 December 2011	7571924	Certificate renewal and removal of unused subcontractors. Beam One LLC, Denver, Advanced Medical Solutions, Winsford, Riverside Medical Packaging, Derby, BSN Medical, Lancs, Beam One LLC, San Diego, Codan Steritex, Denmark, NAMSA, Ohio, Pharmaplast, Egypt, Iotron Industries Canada, Steris Corporation, Ontario, Beam One, Ohio, Smith & Nephew Inc., Florida and Coloplast Corp., MN.

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Page 3 of 10

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Date	Reference Number	Action
18 February 2013	7858491	Update to trading name for Synergy Health subcontractor locations (formerly Isotron); removal of subcontractor Isotron Laboratories, Swindon; addition of subcontractor Chemviron Carbon Ltd; addition of subcontractor Biodaptive LLC.
19 December 2014	8225325	Addition of crucial suppliers Johnson Matthey plc, Azelis Life Sciences Ltd, SQM-SA Chile (3 sites), Medichem S.A., Azelis (Shanghai), PLIVA Croatia Ltd and Teva API B.V. Addition of significant subcontractor Shanghai ISO Medical Products Co., Ltd.
20 October 2015	8333800 8333612 8418001	Extension to scope to include hydrosurgery systems for wound debridement. Addition of significant subcontractors for manufacture (NPA De México S. de R.L. de C.V.; Smith & Nephew Inc) and ETO sterilisation (Sterigenics US LLC) for Versajet. Addition of significant subcontractors for manufacture and control of sterilisation for hydrocolloid dressings (Euromed Inc); gel and gauze dressings (Winner Industries) and NPWT systems and associated foam dressing kits (Smith & Nephew Inc Endoscopy, Vention Medical, Harmac Medical Products).

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Date	Reference Number	Action
09 December 2015	8440432	Removal of significant subcontractor, Smith & Nephew (Alberta).
02 March 2016	8480952	Extension to scope to include abdominal dressing kits for use with NPWT. Addition of significant subcontractor for software development of Renasys (Plexus).
17 June 2016	8487212	Addition of significant subcontractor, Steripack, Malaysia for manufacture and control of sterilisation of Biobrane; extension to scope to include wound dressings utilising animal derived materials (porcine gelatin).
26 July 2016	8544325 8514831	Addition of Smith & Nephew, Inc as significant subcontractor for manufacture and control of sterilisation of RENASYS soft port foam dressing kits. Extension to scope to include drain kits and accessory kits for use with Negative Pressure Wound Therapy.

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Page 5 of 10

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Date	Reference Number	Action
30 November 2016	8632203  8429534	Certificate Renewal. Addition of significant subcontractors Flextronics Design S.r.l and Flextronics International Inc for software and design of PICO. Removal of significant subcontractors Chemviron, Biodaptive, Avail Medical Products, Hardwood Products, Karl Otto Braun and Flexmedical Dallas. Gelita listed as crucial supplier. Extension to scope to include superabsorbers. Addition of Lohmann & Rauscher for manufacture and control of sterilisation of Duramax.
16 February 2017	8676637	Addition of gamma sterilisation services for Synergy Health Sterilisation, Daventry.
03 May 2017	8712342	Addition of Gelita USA as a crucial supplier.
16 June 2017	8647800	Addition of Aspen Medical Europe Limited as a significant subcontractor. Addition of Aspen Surgical Products and Specialist Fibres and Materials Limited as a crucial supplier.

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Page 6 of 10

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Date	Reference Number	Action
21 July 2017	8762343	Addition of Aspen Surgical Products as a Finished Device Supplier. Removal of Aspen Europe Limited as a Finished Device Supplier. Addition of Sterigenics US LLC (Gurnee) for gamma sterilisation.
04 January 2018	8857448	Addition of significant subcontractors Plexus (manufacture) and PA Consulting (design and software).
03 April 2018	8887161	Addition of significant subcontractors Midwest Sterilisation Corporation as ETO Sterilization, and Encube Ethicals Pvt. Ltd. For Manufacture. Amendment to scope to include 'Those aspects of Annex II relating to securing and maintaining sterility in the assembly of procedure packs in accordance with Article 12 of the Medical Device Directive.'
20 November 2018	8902999	Addition of Suzhou CNNC Huadong for sterilisation of Bactigras. Removal of significant subcontractors Azelis Life Science Ltd, Gelita Sweden AB and Smith & Nephew Inc.
23 February 2019	9666435	Addition of authorised representative Smith & Nephew Orthopaedics GmbH. Administrative corrections to address details for, Speciality Fibres and Materials Ltd, Sterigenics UK Limited and Synergy Health Sterilisation.
27 February 2019	7779270	Traceable to NB 0086.

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Page 7 of 10

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Date	Reference Number	Action
31 January 2020	3054769	<p>Certificate renewal</p> <p>Addition of sub-contractors; Isomedix Operations Inc, Shanghai JPY ION-TECH, Synergy Health (Suzhou), Sterigenics Shanghai ETO, Synergy Health AST LLC, Synergy Health Ireland and Plexus Corp. UK.</p> <p>Removal of sub-contractors; Flextronics International, Plexus Corp. USA, PA Consulting Services and Plexus Manufacturing SDN BHD.</p> <p>Sub-contractor name change from Vention Medical, Inc. to Viant Medical, Inc.</p> <p>Administrative updates to correct address information for the following sub-contractors; Avery Dennison, Chester Medical Solutions, Derma Sciences, Flextronics (Shanghai), Lantor (UK) Limited, Lohman &amp; Rauscher, NPA de Mexico S. de R.L. de C.V., Perstorp Specialty Chemicals, Smith &amp; Nephew Medical (Suzhou) Limited, Sterigenics UK Limited, Suzhou CNNC, Synergy Health Sterilisation UK Ltd in Daventry, Synergy Health Sterilisation UK Ltd in Reading and Winner Medical Co., Ltd.</p> <p>Inclusion of product supplementary information table</p> <p>Removal of TIO NPWT system from scope of certification due to discontinuation of product.</p>

**Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3**

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Date	Reference Number	Action
30 November 2021	3513597	<p>Removal of references to CE 650269, CE 01409 and CE 521887 from supplementary information table, following cancellation of these certificates.</p> <p>Update to address for Flextronics Technology (Shenzhen) Co. Ltd.</p> <p>Addition of Sterigenics US, LLC (California), Mediplast Israel Ltd. and STERIS AST CZ s.r.o. (Velka Bites) as subcontractors for ETO Sterilization.</p> <p>Addition of Materion Corporation as a Crucial Supplier.</p> <p>Addition of Zhongjin Irradiation WuHan Co., Ltd. as a subcontractor for Radiation (Gamma Sterilization).</p> <p>Addition of Isomedix Operations, Inc. (2 Nucifora Boulevard, Chester) as a subcontractor for E Beam Sterilization.</p> <p>Addition of Winner Medical (Chongyang) Co., Ltd. as a subcontractor for Control of Sterilization and Manufacture.</p> <p>Change of subcontractor name from Synergy Health (Suzhou) Sterilization Technologies Ltd to STERIS Sterilization Technologies (Suzhou) Ltd.</p> <p>Removal of Aspen Surgical Products, Inc. as a Finished Device Supplier.</p> <p>Removal of SteriPack Asia (M) Sdn Bhd (Selangor) as a subcontractor for Control of Sterilization and Manufacture.</p> <p>Removal of Winner Medical Co., Ltd. as a subcontractor for Control of Sterilization and Manufacture.</p>

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Date	Reference Number	Action
28 September 2022	3753998	Subcontractor name change from Flextronics Technology (Shenzhen) Co. Ltd. to Flextronics Medical Device Manufacturing (Shenzhen) Co., Ltd. Subcontractor addition of Andover Healthcare Inc., 9 Faranas Drive, Salisbury MA 01952, United States of America.
27 October 2023	3817443	Removal of reference to CE 01714 from supplementary information table following cancellation of the certificate from: - Antimicrobial Wound Dressings - Wound Dressings containing porcine gelatine Removal of Wound Preparation Devices from supplementary information table following product discontinuation. Addition of critical subcontractors for manufacture and ETO sterilisation.
15 December 2023	30074443	Addition of a critical subcontractor for EtO sterilisation.

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Page 10 of 10

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15 December 2023

Smith & Nephew Medical Ltd  
101 Hessle Road  
Hull  
HU3 2BN  
United Kingdom

To whom it may concern,

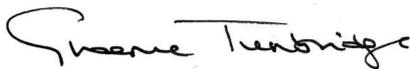
The transitional provisions specified in MDR Article 120(3) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26<sup>th</sup> May 2021.

This letter is to confirm that BSI has reviewed and approved the change(s) detailed in the table below. These changes do not represent a significant change in design or intended purpose under MDR Article 120(3) and as per the guidance provided in MDCG 2020-3. The related MDD certificate specified below remains valid until the expiry date specified on the certificate.

<b>Certificate</b>	<b>Directive and Annex</b>	<b>Reference Number</b>	<b>Changes approved</b>
CE 00356	93/42/EEC Annex II excluding Section 4	30074443	Addition of a critical subcontractor for EtO sterilisation.

Should you have any queries concerning your certification, or if we can be of further assistance to you, please contact your BSI Scheme Manager.

Yours sincerely,



Graeme Tunbridge  
Senior Vice President, Medical Devices

## EUROPEAN DECLARATION OF CONFORMITY

This Declaration confirms that the product listed below meets the Essential Requirements set out in Annex I of the Council Directive 93/42/EEC (as amended).

- Manufacturer's Name :** Smith & Nephew Medical Limited,  
**Business Address :** 101 Hessele Road,  
Hull,  
HU3 2BN,  
United Kingdom.
- Authorised Representative:** Smith & Nephew Orthopaedics GmbH,  
Alemannenstraße 14,  
78532 Tuttlingen,  
Germany
- Medical Devices :** RENASYS TOUCH Negative Pressure Wound  
Therapy (NPWT) System Pump  
**Classification :** Class IIb  
**GMDN Code and Term :** 47955 Negative-pressure wound therapy system,  
**Scope of Application :** battery-powered, reusable
- Declaration :** All batches supplied to which the Declaration of  
Conformity Procedure has been applied.  
Conformity of the product has been assessed in  
accordance with Annex II of the Directive. A dossier  
of technical documentation, as required by the  
Directive is available. The product listed is designed,  
manufactured and tested in accordance with the  
information set out in the dossier.
- Verification Certificate(s):** EC Certificate No. CE 00356 Full Quality Assurance.  
Notified Body No. 2797 (British Standards Institute)  
British Standards Institute. Certificate No. MD 76718  
Quality Management System (BS EN ISO 13485)  
British Standards Institute. Certificate No. FM 24676  
Quality Management System (BS EN ISO 9001)
- Standards Applied :** BS EN ISO 13485:2016  
BS EN ISO 9001:2015  
BS EN ISO 14971:2019  
BS EN ISO 10993-1:2009/AC:2010  
BS EN ISO 15223-1:2016  
BS EN ISO 780:2015  
BS EN ISO 14644-1:2015  
BS EN 60601-1:2012 Edition 3.1  
BS EN 60601-1-2:2014 Edition 4  
BS EN 60601-1-6:2010 Edition 3.0  
BS EN 60601-1-8:2006 Edition 2

**Smith & Nephew Medical Limited**  
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**SmithNephew**

BS EN 60601-1-11:2015 Edition 2 BS EN 62133:2012  
BS EN 62366:2007 Edition 1  
BS EN 62304:2006 Edition 1  
BS EN 62321:2009  
CENELEC 50581:2012  
WEEE Directive 2012/19/EU  
Restriction of Hazardous Substances (RoHS) Directive –  
2011/65/EU

**PRODUCT CODES**

Code	Size
66801280	N/A
66801281	N/A
66802134	N/A

**Authorised Signatory :**

**Name :**

KEN FELEUSSON

**Position :**

SENIOR REGULATORY AFFAIRS MANAGER

**Signed :**



---

**Dated :**

04 NOV 2021

**Certificate Reference :**

HU/110 issue 12

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## EUROPEAN DECLARATION OF CONFORMITY<sup>1</sup>

Declaration confirms that the product listed below meets Regulation 2017/745 and is issued under the sole responsibility of Smith & Nephew Medical Ltd.<sup>2</sup>

<b>Manufacturer's Name<sup>3</sup></b>	Smith & Nephew Medical Limited
<b>Business Address<sup>4</sup></b>	101 Hessle Road, Hull, HU3 2BN, United Kingdom
<b>Single Registration Number (SRN)<sup>5</sup></b>	GB-MF-000017580
<b>European Authorised Representative<sup>6</sup></b>	Smith & Nephew Operations B.V.
<b>Business Address<sup>7</sup></b>	Bloemlaan 2, 2132 NP Hoofddorp, Netherlands
<b>Product Name:</b> <i>(see attached schedule for product codes/catalogue numbers)<sup>8</sup></i>	RENASYS Touch Canisters
<b>Intended Use<sup>9</sup></b> <i>See table for other languages</i>	Intended to be used in conjunction with Smith & Nephew Negative Pressure Wound Therapy (NPWT) systems.
<b>Conformity Assessment Procedure (Annex)<sup>10</sup></b>	N/A
<b>Notified Body Name<sup>11</sup></b>	N/A
<b>Notified Body Number<sup>12</sup></b>	N/A
<b>Verification Certificate(s)<sup>13</sup></b>	N/A

### Signed on behalf of Smith & Nephew Medical Limited<sup>14</sup>

<b>Signature<sup>15</sup></b>	<p>DocuSigned by:     Signer Name: Ken Fergusson          Signing Reason: I approve this document          Signing Time: 07-Apr-2022   17:58:17 BST          70CA089D3CF744E288FB372950E2A83E</p>
<b>Name<sup>16</sup></b>	Ken Fergusson

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<b>Position<sup>17</sup></b>	Senior Regulatory Affairs Manager
<b>Date<sup>18</sup></b>	07-Apr-2022   17:58:33 BST
<b>Location<sup>19</sup></b>	Hull
<b>Declaration of Conformity Reference<sup>20</sup></b>	DOC-WMTF-005/V2

**Product Schedule<sup>21</sup>**

<b>Product Code / Catalogue Number<sup>22</sup></b>	<b>Product Description or Product Variant<sup>23</sup></b>	<b>Risk Classification<sup>24</sup></b>	<b>Basic UDI<sup>25</sup></b>
66801273	RENASYS Touch Canister with Solidifier 300ml	I	5000223SN000095RR
66801274	RENASYS Touch Canister with Solidifier 800ml	I	5000223SN000095RR
66801275	RENASYS Touch Canister without Solidifier 300ml	I	5000223SN000095RR

**Standard/Common Specification Number<sup>27</sup>**

EN ISO 13485:2016
EN 60601-1:2005 3.1 edition
EN 60601-1-11:2015 2nd edition
EN ISO 14971:2019
EN 62366-1:2015
EN ISO 15223-1:2021
EN ISO 780:2015
ISO 10993-1:2018
EN ISO 20417:2021
EN ISO 14644-1:2015

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**Intended Use European Language Translations<sup>28</sup>:**

Language <sup>29</sup>	Code	Intended Use
<b>Bulgarian</b>	BG	Предназначени за употреба съвместно със системите за терапия на рани с отрицателно налягане (NPWT) на Smith & Nephew.
<b>Croatian</b>	HR	Namijenjeno za upotrebu sa sustavima Smith & Nephew za liječenje rana negativnim tlakom.
<b>Czech</b>	CZ	Mělo by se využívat ve spojení se systémy podtlakové léčby ran (NPWT) společnosti Smith & Nephew.
<b>Danish</b>	DK	Beregnet til at blive brugt sammen med Smith & Nephews systemer til sårbehandling med negativt tryk (NPWT).
<b>Dutch</b>	NL	Bedoeld voor gebruik in combinatie met systemen voor negatieve-drukwondtherapie (NPWT-systemen) van Smith & Nephew.
<b>Estonian</b>	EE	Mõeldud kasutamiseks koos Smith & Nephew alarõhuga haavaravisüsteemidega.
<b>Finnish</b>	FI	Tarkoitettu käytettäväksi yhdessä Smith & Nephew'n haavan alipaineimuhoidojärjestelmien (NPWT-järjestelmien) kanssa.
<b>French</b>	FR	Destiné à être utilisé conjointement avec les systèmes de traitement des plaies par pression négative de Smith & Nephew (NPWT).
<b>German</b>	DE	Zur Verwendung gemeinsam mit den Smith & Nephew Unterdruck-Wundtherapie(NPWT)Systemen.
<b>Greek</b>	GR	Προορίζεται για χρήση σε συνδυασμό με τα συστήματα θεραπείας τραύματος με αρνητική πίεση (NPWT) της Smith & Nephew.
<b>Hungarian</b>	HU	Használatra a Smith & Nephew negatív nyomású sebkezelési (Negative Pressure Wound Therapy, NPWT) rendszerekkel együtt javallott.
<b>Italian</b>	IT	Previsto per l'uso con i sistemi di terapia a pressione negativa per il trattamento delle ferite (NPWT) di Smith & Nephew.
<b>Latvian</b>	LV	Paredzēts lietošanai kopā ar Smith & Nephew negatīvā spiediena brūču terapiju (negative pressure wound therapy jeb NPWT) sistēmām.
<b>Lithuanian</b>	LT	Skirta naudoti kartu su „Smith & Nephew“ neigiamo slėgio žaizdų terapijos (angl. „Negative Pressure Wound Therapy“, NPWT) sistemomis.
<b>Polish</b>	PO	Przeznaczony do stosowania w połączeniu z systemami podciśnieniowego leczenia ran (NPWT) Smith & Nephew.
<b>Portuguese</b>	PT	Destinam-se a ser utilizados com conjunto com sistemas de terapia de feridas por pressão negativa (TFPN) da Smith & Nephew.
<b>Romanian</b>	RO	Este destinat utilizării în asociere cu sistemele de terapie cu presiune negativă pentru vindecarea plăgilor (NPWT) Smith & Nephew.
<b>Slovak</b>	SK	Je určený na použitie spolu so systémami negatívnej tlakovej liečby rán Smith & Nephew (NPWT).
<b>Slovenian</b>	SL	Predvideno za uporabo v povezavi s sistemi Smith & Nephew za zdravljenje ran z negativnim tlakom (NPWT).
<b>Spanish</b>	ES	Indicado para utilizarse junto con los sistemas de terapia de heridas de presión negativa (TPN) de Smith & Nephew.
<b>Swedish</b>	SE	Avsedd att användas tillsammans med Smith & Nephew:s system för sårbehandling med negativt tryck (NPWT).

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Language <sup>29</sup>	Code	No.	Translated Terms
		1	ЕВРОПЕЙСКА ДЕКЛАРАЦИЯ ЗА СЪОТВЕТСТВИЕ
		2	Декларацията потвърждава, че посоченият по-долу продукт съответства на: Регламент 2017/745, [въведете друго уместно европейско законодателство, според приложимото] и се издава единствено на отговорност на име на законния производител
		3	Име на производител
		4	Бизнес адрес
		5	Единен регистрационен номер (ЕРН)
		6	Упълномощен представител за Европа
		7	Бизнес адрес
		8	Име на продукт: (вижте приложния опис за продуктови кодове/каталожни номера)
		9	Предназначение: Вижте таблицата за други езици
		10	Процедура за оценяване на съответствието (Приложение)
		11	Име на нотифициран орган
		12	Номер на нотифициран орган
		13	Сертификат(и) за проверка
		14	Подписан от името на име на законния производител
		15	Подпис
		16	Име
		17	Длъжност
		18	Дата
		19	Местоположение
		20	Справка за декларация за съответствие
		21	Продуктов опис
		22	Продуктов код / Каталоген номер
		23	Описание на продукта или Вариант на продукта
		24	Класификация в зависимост от риска
		25	Основен уникален идентификатор на изделията - идентификатор на изделията
<b>Bulgarian:</b>	<b>BG</b>		

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	26	Стандарти / Обща(и) спецификация(и)
	27	Стандарт/Номер на обща спецификация
	28	Предназначение: Преводи на европейски езици
	29	Език

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Language <sup>29</sup>	Code	No.	Translated Terms
		1	EUROPSKA IZJAVA O SUKLADNOSTI
		2	Izjavom se potvrđuje da je niže navedeni proizvod u skladu s: Uredbama 2017/745, [unesite ostale mjerodavne Europske zakone, kako je primjenjivo]. Odgovornost za njeno izdavanje snosi isključivo [naziv proizvođača]
		3	Naziv proizvođača
		4	Adresa poslovanja
		5	Jedinstveni registracijski broj (SRN)
		6	Ovlašteni zastupnik za Europu
		7	Adresa poslovanja
		8	Naziv proizvođača: (šifre proizvoda/kataloške brojeve potražite u priloženom dodatku)
		9	Namjena: Proučite tablicu za ostale jezike
		10	Postupak ocjenjivanja sukladnosti (Prilog)
		11	Naziv prijavljenog tijela
		12	Broj prijavljenog tijela
		13	Potvrda (potvrde) o provjeri
		14	Potpisao/-la u ime [naziv proizvođača]
		15	Potpis
		16	Ime i prezime
		17	Funkcija
		18	Datum
		19	Mjesto
		20	Oznaka izjave o sukladnosti
		21	Dodatak za proizvod
		22	Šifra proizvoda / kataloški broj
		23	Opis proizvoda ili inačica proizvoda
		24	Razvrstavanje rizika
<b>Croatian:</b>	<b>HR</b>		

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	25	Osnovna jedinstvena identifikacija proizvoda-identifikator proizvoda (UDI-DI)
	26	Norme / Zajednička specifikacija (zajedničke specifikacije)
	27	Norma / Broj zajedničke specifikacije
	28	Namjena: prijevodi na europske jezike
	29	Jezik

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Language <sup>29</sup>	Code	No.	Translated Terms
		1	EVROPSKÉ PROHLÁŠENÍ O SHODĚ
		2	Prohlášení potvrzuje, že níže uvedený výrobek splňuje nařízení 2017/745 [případně doplňte další příslušné evropské právní předpisy], a je vydáno na výhradní zodpovědnost [oficiální název výrobce]
		3	Název výrobce
		4	Adresa místa podnikání
		5	Jediné registrační číslo
		6	Oprávněný zástupce pro Evropu
		7	Adresa místa podnikání
		8	Název výrobku: (kód výrobku / katalogové číslo viz příložený soupis)
		9	Určené použití: Viz tabulka pro další jazyky
		10	Postup posuzování shody (příloha)
		11	Název oznámeného subjektu
		12	Číslo oznámeného subjektu
		13	Osvědčení o ověření
		14	Podpsáno jménem [oficiální název výrobce]
		15	Podpis
		16	Jméno
		17	Pozice
		18	Datum
		19	Místo
		20	Prohlášení o shodě – reference
		21	Soupis výrobků
		22	Kód výrobku / katalogové číslo
		23	Popis výrobku nebo varianta výrobku
		24	Klasifikace rizik
<b>Czech:</b>	<b>CZ</b>		

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	25	Základní UDI-DI
	26	Normy / společné specifikace
	27	Číslo normy / společné specifikace
	28	Zamýšlené použití: překlady do evropských jazyků
	29	Jazyk

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Language <sup>29</sup>	Code	No.	Translated Terms
		1	EUROPÆISK OVERENSTEMMELSESEKTLÆRING
		2	Erklæringen bekræfter, at produkterne angivet herunder overholder: Forordning 2017/745, [indsæt anden gældende europæisk lovgivning hvis relevant] og er udstedt med eneansvar for [Juridisk fabrikantnavn]
		3	Fabrikantens navn
		4	Virksomhedsadresse
		5	Individuelt registreringsnummer (Single Registration Number, SRN)
		6	Autoriseret europæisk repræsentant
		7	Virksomhedsadresse
		8	Produktnavn: (se vedlagte bilag for produktkoder/katalognumre)
		9	Tilsliget brug: Se tabel for andre sprog
		10	Procedure for overensstemmelsesvurdering (bilag)
		11	Bemyndiget organ, navn
		12	Bemyndiget organ, nummer
		13	Verifikationscertifikat(er)
		14	Underskrevet på vegne af [Juridisk fabrikantnavn]
		15	Underskrift
		16	Navn
		17	Position
		18	Dato
		19	Placering
		20	Overensstemmelseerklæring, reference
		21	Produktbilag
		22	Produktkode/katalognummer
		23	Produktbeskrivelse eller produktvariant
		24	Risikoklasse
<b>Danish:</b>	<b>DK</b>		

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	25	Grundlæggende UDI-DI
	26	Standarder/almindelig(e) specifikation(er)
	27	Standard/almindeligt specifikationsnummer
	28	Tilsligtet brug: Oversættelser på europæiske sprog
	29	Sprog

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Language <sup>29</sup>	Code	No.	Translated Terms
<b>Dutch:</b>	<b>NL</b>	1	EUROPESE CONFORMITEITSVERKLARING
		2	Deze verklaring bevestigt dat het hieronder vermelde product voldoet aan: Verordening 2017/745, [andere relevante Europese wetgeving invoegen indien van toepassing] en wordt verstrekt onder de exclusieve verantwoordelijkheid van [wettige naam van fabrikant]
		3	Naam van fabrikant
		4	Bedrijfsadres
		5	SRN (single registration number: afzonderlijk registratienummer)
		6	Geautoriseerde vertegenwoordiger voor Europa
		7	Bedrijfsadres
		8	Productnaam: (zie bijgevoegd aanhangsel voor productcodes/catalogusnummers)
		9	Beoogd gebruik: Zie tabel voor andere talen
		10	Procedure voor conformiteitsbeoordeling (bijlage)
		11	Naam van aanmeldingsinstantie
		12	Nummer van aanmeldingsinstantie
		13	Verificatiecertificaat/-certificaten
		14	Ondertekend namens [wettige naam van fabrikant]
		15	Handtekening
		16	Naam
		17	Functie
		18	Datum
		19	Plaats
		20	Referentie conformiteitsverklaring
		21	Productschema
		22	Productcode/catalogusnummer
		23	Productbeschrijving of productvariant

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	24	Risicoclassificatie
	25	Basis UDI-DI
	26	Standaarden/Algemene specificatie(s)
	27	Standaard/Algemeen specificatienummer
	28	Beoogd gebruik: vertalingen in Europese talen
	29	Taal

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Language <sup>29</sup>	Code	No.	Translated Terms
		1	EUROOPA VASTAVUSDEKLARATSIOON
		2	Selle deklaratsiooniga kinnitame allpool loetletud toote vastavust: määrusele 2017/745 [sisestage muu Euroopa õigusakt, kui on kohaldatav] ning see väljastatakse [seadusliku tootja nimi] ainuvastutusel
		3	Tootja nimi
		4	Registreeritud aadress
		5	Unikaalne registreerimisnumber (SRN)
		6	Volitatud esindaja Euroopas
		7	Registreeritud aadress
		8	Toote nimetus: (tootekoode/katalooginumbreid vt lisatud tabelist)
		9	Ettenähtud kasutusotstarve: Teisi keeli vt tabelist
		10	Vastavushindamise protseduur (lisa)
		11	Teavitatud asutuse nimetus
		12	Teavitatud asutuse number
		13	Kinnitussertifikaat/-sertifikaadid
		14	Allkirjastanud [seadusliku tootja nimi]
		15	Allkiri
		16	Nimi
		17	Ametikoht
		18	Kuupäev
		19	Asukoht
		20	Vastavusdeklaratsiooni viide
		21	Toote tabel
		22	Tootekood/katalooginumbr
		23	Toote kirjeldus või toote variant
		24	Riski klassifikatsioon
<b>Estonian:</b>	<b>EE</b>		

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	25	Põhiline UDI-DI
	26	Standardid / ühtsed tehnilised tingimused
	27	Standardi / ühtsete tehniliste tingimuste number
	28	Ettenähtud kasutusotstarve Tõlked Euroopa keeltesse
	29	Keel

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Language <sup>29</sup>	Code	No.	Translated Terms
<b>Finnish:</b>	<b>FI</b>	1	EUROOPPALAINEN VAATIMUSTENMUKAISUUSVAKUUTUS
		2	Vakuuksella vahvistetaan, että jäljempänä mainittu tuote täyttää: Asetuksen 2017/745, [tähän tulee lisätä muu asiaan liittyvä eurooppalainen lainsäädäntö sikäli kuin sitä on] mukaiset vaatimukset, ja annetusta vakuutuksesta vastuussa on yksinomaan [laillisen valmistajan nimi]
		3	Valmistajan nimi
		4	Toimipaikan osoite
		5	Rekisterinumero (SRN)
		6	Eurooppalainen valtuutettu edustaja
		7	Toimipaikan osoite
		8	Tuotteen nimi: (ks. liitteestä tuotekoodit/luettelonumerot)
		9	Käyttötarkoitus: Taulukossa esitetään muut kieliversiot
		10	Vaatimustenmukaisuuden arviointimenettely (Liite)
		11	Ilmoitetun laitoksen nimi
		12	Ilmoitetun laitoksen numero
		13	Tarkastustodistus (-todistukset)
		14	Allekirjoitettu puolesta [laillisen valmistajan nimi]
		15	Allekirjoitus
		16	Nimi
		17	Asema
		18	Päiväys
		19	Paikka
		20	Vaatimustenmukaisuusvakuutuksen viite
		21	Tuoteluettelo
		22	Tuotekoodi / Luettelonumero
		23	Tuotekuvaus tai tuotevariantti

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	24	Riskiluokitus
	25	Perus-UDI-DI-tunniste
	26	Standardit / Yhteinen eritelmä (tai monikossa)
	27	Standardin/yhteisen eritelmän numero
	28	Käyttötarkoitus Käännökset Euroopan kielillä
	29	Kieli

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Language <sup>29</sup>	Code	No.	Translated Terms
<b>French:</b>	<b>FR</b>	1	DÉCLARATION DE CONFORMITÉ EUROPÉENNE
		2	La déclaration confirme que le produit repris ci-dessous est conforme au : Règlement (UE) 2017/745 [insérer au besoin toute autre législation européenne pertinente] et est publiée sous la seule responsabilité de Nom du fabricant légal
		3	Nom du fabricant
		4	Adresse professionnelle
		5	Numéro d'enregistrement unique
		6	Mandataire établi dans l'UE
		7	Adresse professionnelle
		8	Nom du produit : (voir l'annexe jointe pour les codes de produit/références catalogue)
		9	Usage prévu : Voir le tableau pour les autres langues
		10	Procédure d'évaluation de la conformité (Annexe)
		11	Nom de l'organisme notifié
		12	N° de l'organisme notifié
		13	Certificat(s) de vérification
		14	Signé au nom de Nom du fabricant légal
		15	Signature
		16	Nom
		17	Poste
		18	Date
		19	Adresse
		20	Référence de la déclaration de conformité
		21	Annexe de produit
		22	Code du produit / Référence catalogue du produit
		23	Description du produit ou variante du produit

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	24	Classe de risque
	25	Identifiant « dispositif » IUD (IUD-ID)
	26	Normes / Spécification(s) commune(s)
	27	N° de la norme/spécification commune
	28	Usage prévu : traduction dans des langues européennes
	29	Langue

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Language <sup>29</sup>	Code	No.	Translated Terms
		1	EUROPÄISCHE KONFORMITÄTSERKLÄRUNG
		2	Mit dieser Erklärung wird bestätigt, dass das unten aufgeführte Produkt den folgenden Anforderungen entspricht: Verordnungen 2017/745, [ggf. andere einschlägige europäische Rechtsvorschriften einfügen]. Die alleinige Verantwortung für die Ausstellung dieser Konformitätserklärung trägt [Name des Herstellers]
		3	Name des Herstellers
		4	Geschäftsadresse
		5	Einmalige Registrierungsnummer (SRN)
		6	Europäischer Bevollmächtigter
		7	Geschäftsadresse
		8	Produktname: (Produktcodes/Katalognummern siehe beigefügtes Verzeichnis)
		9	Verwendungszweck: Andere Sprachen siehe Tabelle
		10	Konformitätsbewertungsverfahren (Anhang)
<b>German</b>	<b>DE</b>	11	Name der benannten Stelle
		12	Nummer der benannten Stelle
		13	Prüfzertifikat(e)
		14	Unterzeichnet im Auftrag von Name des Herstellers
		15	Unterschrift
		16	Name
		17	Position
		18	Datum
		19	Standort
		20	Konformitätserklärung – Referenz
		21	Produktverzeichnis
		22	Produktcode/Katalognummer
		23	Produktbeschreibung oder Produktvariante

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	24	Risikoklassifizierung
	25	Basis-UDI-DI
	26	Normen/Gemeinsame Spezifikation(en)
	27	Nummer der Norm/Gemeinsamen Spezifikation
	28	Verwendungszweck: Übersetzung in europäische Sprachen
	29	Sprache

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<b>Greek:</b>	<b>GR</b>	1	ΕΥΡΩΠΑΪΚΗ ΔΗΛΩΣΗ ΣΥΜΜΟΡΦΩΣΗΣ
		2	Η δήλωση επιβεβαιώνει ότι το προϊόν που αναφέρεται παρακάτω πληροί: τους κανονισμούς 2017/745, [συμπληρώστε άλλη σχετική ευρωπαϊκή νομοθεσία ανάλογα με την περίπτωση] και εκδίδεται υπό την αποκλειστική ευθύνη του [επωνυμία νόμιμου κατασκευαστή]
		3	Επωνυμία κατασκευαστή
		4	Διεύθυνση επιχείρησης
		5	Ενιαίος αριθμός καταχώρισης (SRN)
		6	Εξουσιοδοτημένος αντιπρόσωπος στην Ευρώπη
		7	Διεύθυνση επιχείρησης
		8	Όνομασία προϊόντος: (βλ. συνημμένο παράρτημα κωδικών προϊόντων/αριθμών καταλόγου)
		9	Προβλεπόμενη χρήση: βλ. πίνακα για άλλες γλώσσες
		10	Διαδικασία εκτίμησης της συμμόρφωσης (παράρτημα)
		11	Επωνυμία κοινοποιημένου οργανισμού
		12	Αριθμός κοινοποιημένου οργανισμού
		13	Πιστοποιητικό(ά) επαλήθευσης
		14	Υπογραφή εξ' ονόματος του [επωνυμία νόμιμου κατασκευαστή]
		15	Υπογραφή
		16	Όνοματεπώνυμο
		17	Τίτλος
		18	Ημερομηνία
		19	Τοποθεσία
		20	Αναφορά δήλωσης συμμόρφωσης
		21	Παράρτημα προϊόντων
		22	Κωδικός προϊόντος/Αριθμός καταλόγου
		23	Περιγραφή προϊόντος ή παραλλαγής προϊόντος
		24	Ταξινόμηση κινδύνου
		25	Βασικό UDI-DI

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	26	Πρότυπα/Κοινή(ές) προδιαγραφή(ές)
	27	Αριθμός προτύπου/κοινής προδιαγραφής
	28	Προβλεπόμενη χρήση: μεταφράσεις σε ευρωπαϊκές γλώσσες
	29	Γλώσσα

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Language <sup>29</sup>	Code	No.	Translated Terms
		1	EURÓPAI MEGFELELŐSÉGI NYILATKOZAT
		2	A nyilatkozat megerősíti, hogy az alább felsorolt termék megfelel a következőknek: A 2017/745 rendeletek, [értelemszerűen illeszse be ide az egyéb fontos európai jogszabályokat], és kiadása a gyártó hivatalos neve kizárólagos felelősségére történik
		3	A gyártó neve
		4	Székhelye
		5	Egyedüli nyilvántartási szám (SRN)
		6	Meghatalmazott európai képviselő
		7	Székhelye
		8	A termék neve: (lásd a mellékelt listát a termékkódokat/katalógusszámokat illetően)
		9	Rendeltetésszerű használat: Az egyéb nyelveket lásd a táblázatban
		10	Megfelelőségértékelési eljárás (melléklet)
		11	Az értesített testület neve
		12	Az értesített testület száma
		13	Hitelesítési tanúsítvány(ok)
		14	Aláírva a gyártó hivatalos neve nevében
		15	Aláírás
		16	Név
		17	Beosztás
		18	Dátum
		19	Hely
		20	A megfelelőségi nyilatkozat hivatkozása
		21	Terméklista
		22	Termékkód/katalógusszám
		23	A termék leírása vagy termékváltozat
		24	Kockázatbesorolás
		25	Alap UDI-DI
<b>Hungarian:</b>	<b>HU</b>		

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	26	Szabványok/gyakori előírás(ok)
	27	A szabvány/gyakori előírás száma
	28	A rendeltetészerű használat európai nyelvre történt fordítása
	29	Nyelv

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Language <sup>29</sup>	Code	No.	Translated Terms
<b>Italian:</b>	<b>IT</b>	1	DICHIARAZIONE DI CONFORMITÀ EUROPEA
		2	La dichiarazione conferma che il prodotto menzionato di seguito è conforme a: Regolamento 2017/745, [inserire altre normative europee pertinenti per quanto applicabile], ed è rilasciata sotto l'esclusiva responsabilità del fabbricante legale
		3	Nome del fabbricante
		4	Indirizzo aziendale
		5	Numero di registrazione unico (Single Registration Number, SRN)
		6	Rappresentante europeo autorizzato
		7	Indirizzo aziendale
		8	Nome del prodotto: (vedere il prospetto allegato per i codici di prodotto/numeri di catalogo)
		9	Uso previsto: vedere la tabella per le altre lingue
		10	Procedura di valutazione di conformità (Allegato)
		11	Nome dell'organismo notificato
		12	Numero dell'organismo notificato
		13	Certificazione/i di verifica
		14	Firmato in nome e per conto di: (nome del fabbricante legale)
		15	Firma
		16	Nome
		17	Posizione professionale
		18	Data
		19	Sede
		20	Riferimento per la Dichiarazione di conformità
		21	Prospetto prodotti
		22	Codice prodotto/Numero di catalogo
		23	Descrizione del prodotto o variante di prodotto
		24	Classificazione del rischio
		25	Codice UDI-DI

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	26	Norme/Specifiche comuni
	27	Numero norma/specifica comune
	28	Usò previsto: traduzioni nelle lingue europee
	29	Lingua

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Language <sup>29</sup>	Code	No.	Translated Terms
Latvian:	LV	1	EIROPAS ATBILSTĪBAS DEKLARĀCIJA
		2	Deklarācija apliecina, ka tālāk norādītais produkts atbilst: Regulām 2017/745, [ievietojiet citus atbilstošus Eiropas tiesību aktus, kā nepieciešams], un tā ir izsniegta tikai uz [ražotāja juridiskais nosaukums] atbildību
		3	Ražotāja nosaukums
		4	Uzņēmuma adrese
		5	Vienotais reģistrācijas numurs (VRN)
		6	Pilnvarotais pārstāvis Eiropā
		7	Uzņēmuma adrese
		8	Produkta nosaukums: (produkta kodus/kataloga numurus skatīt pievienotajā pielikumā)
		9	Paredzētā lietošana: informāciju par citām valodām skatīt tabulā
		10	Atbilstības novērtēšanas procedūra (Pielikums)
		11	Paziņotās struktūras nosaukums
		12	Paziņotās struktūras numurs
		13	Pārbaudes sertifikāts(-i)
		14	Parakstīts [ražotāja juridiskais nosaukums] vārdā
		15	Paraksts
		16	Vārds, uzvārds
		17	Amats
		18	Datums
		19	Vieta
		20	Atbilstības deklarācijas atsauce
		21	Produkta pielikums
		22	Produkta kods/kataloga numurs
		23	Produkta apraksts vai produkta variants
		24	Riska klasifikācija
		25	Pamata UDI-DI

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	26	Standarti/vispārīgā(-s) specifikācija(-s)
	27	Standarts/vispārīgās specifikācijas numurs
	28	Paredzētā lietošana: tulkojumi Eiropas valodās
	29	Valoda

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Language <sup>29</sup>	Code	No.	Translated Terms
		1	Europos Atitikties Deklaracija
		2	Delaracija patvirtina kad toliau išvardyti produktai atitinka: Reglamentą 2017/745, [įterpti kitus taikytinus Europos teisės aktus] ir už jo išdavimą yra visiškai atsakingas [legalus gamintojo vardas].
		3	Gamintojo vardas
		4	Verslo adresas
		5	Bendras Registracijos Numeris (BRN)
		6	Europos igaliojasis atstovas
		7	Verslo adresas
		8	Produkto vardas: (produktų kodus / katalogo numerius žiūrėkite pridedamame tvarkaraštyje)
		9	Paskirtis: kitomis kalbomis žiūrėkite lentelę
		10	Atitikties įvertinimo procedūra (priedas)
		11	Notifikuotosios įstaigos vardas
		12	Notifikuotosios įstaigos numeris
		13	Patvirtinimo Pažymėjimas (-ai)
		14	Pasirašyta (legalaus gamintojo vardas) vardu
		15	Parašas
		16	Vardas
		17	Pozicija
		18	Data
		19	Vieta
		20	Atitikties Deklaracijos Nuoroda
		21	Produkto grafikas
		22	Produkto Kodas/ Katalogo numeris
		23	Produkto Apibūdinimas arba Produkto Variantas
		24	Rizikos Klasifikacija
		25	Pagrindinis UDI
<b>Lithuanian:</b>	<b>LT</b>		

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	26	Standartai / Bendroji specifikacija (-os)
	27	Standartinis / Bendrasis specifikacijos numeris
	28	Europos kalbų vertimas pagal paskirtį
	29	Kalba

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Language <sup>29</sup>	Code	No.	Translated Terms
<b>Polish:</b>	<b>PO</b>	1	EUROPEJSKA DEKLARACJA ZGODNOŚCI
		2	Deklaracja potwierdza, że wymieniony poniżej produkt spełnia wymagania: Rozporządzenia 2017/745 [w razie potrzeby wstawić inne stosowne przepisy europejskie] i jest wydawana na wyłączną odpowiedzialność Nazwa producenta
		3	Nazwa producenta
		4	Adres firmy
		5	Niepowtarzalny numer rejestracyjny (SRN)
		6	Upoważniony przedstawiciel w Unii Europejskiej
		7	Adres firmy
		8	Nazwa produktu: (kody produktów / numery katalogowe zawiera załączony wykaz)
		9	Przeznaczenie: Tekst w innych językach znajduje się w tabeli
		10	Procedura oceny zgodności (załącznik)
		11	Nazwa jednostki notyfikowanej
		12	Numer jednostki notyfikowanej
		13	Certyfikaty weryfikacji
		14	Podpisano w imieniu Nazwa producenta
		15	Podpis
		16	Imię i nazwisko
		17	Stanowisko
		18	Data
		19	Miejsce
		20	Numer referencyjny deklaracji zgodności
		21	Wykaz produktów
		22	Kod produktu / numer katalogowy
		23	Opis produktu lub wariant produktu
		24	Klasyfikacja ryzyka
		25	Kod Basic UDI-DI

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	26	Normy / wspólne specyfikacje
	27	Numer normy / wspólnej specyfikacji
	28	Tłumaczenia tekstu dotyczącego przeznaczenia produktu na języki europejskie
	29	Język

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Language <sup>29</sup>	Code	No.	Translated Terms
<b>Portuguese:</b>	<b>PT</b>	1	DECLARAÇÃO DE CONFORMIDADE EUROPEIA
		2	A declaração confirma que os produtos listados abaixo cumprem: Regulamentação 2017/745, [inserir outra legislação europeia relevante, conforme aplicável] e é emitida sob a responsabilidade única do [Nome legal do fabricante]
		3	Nome do fabricante
		4	Endereço da empresa
		5	Número único de registo (NUR)
		6	Representante Europeu Autorizado
		7	Endereço da empresa
		8	Nome do produto: (consulte o anexo quanto a códigos de produtos/números de catálogo)
		9	Finalidade: Consulte a tabela para outros idiomas
		10	Procedimento de avaliação de conformidade (Anexo)
		11	Nome do organismo notificado
		12	Número do organismo notificado
		13	Certificado(s) de verificação
		14	Assinado em nome de [Nome legal do fabricante]
		15	Assinatura
		16	Nome
		17	Cargo
		18	Data
		19	Localização
		20	Referência de Declaração de conformidade
		21	Anexo do produto
		22	Código de produto / Número de catálogo
		23	Descrição do produto ou variante do produto
		24	Classificação de risco
		25	UDI-DI básico

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	26	Normas / Especificação(ões) comum(ns)
	27	Normas/Número de especificação comum
	28	Traduções da Finalidade para idiomas europeus
	29	Idioma

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Language <sup>29</sup>	Code	No.	Translated Terms
		1	DECLARAȚIE DE CONFORMITATE EUROPEANĂ
		2	Declarația confirmă faptul că produsul specificat mai jos respectă: Regulamentul 2017/745, [introduceți ale acte legislative europene relevante, după caz] și este emis pe propria răspundere a Denumirea juridică a producătorului
		3	Denumirea producătorului
		4	Sediul social
		5	Număr unic de înregistrare (SRN)
		6	Reprezentant european autorizat
		7	Sediul social
		8	Denumirea produsului: (consultați anexa atașată pentru codurile de produs/numerele de catalog)
		9	Utilizare preconizată: consultați tabelul pentru alte limbi
		10	Procedura de evaluare a conformității (Anexă)
		11	Denumirea organismului notificat
		12	Numărul organismului notificat
		13	Certificat(e) de verificare
		14	Semnat în numele Denumirea juridică a producătorului
		15	Semnătură
		16	Nume
		17	Funcție
		18	Data
		19	Loc
		20	Referință pentru declarația de conformitate
		21	Anexa produsului
		22	Cod produs / Număr de catalog
		23	Descrierea produsului sau varianta produsului
		24	Clasificarea riscurilor
		25	UDI-DI de bază
<b>Romanian:</b>	<b>RO</b>		

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	26	Standarde / Specificație(i) comună(e)
	27	Standard / Număr de specificație comună
	28	Utilizare preconizată: traduceri în limbile europene
	29	Limbă

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Language <sup>29</sup>	Code	No.	Translated Terms
		1	VYHLÁSENIE O ZHODE EÚ
		2	Vyhľadanie potvrdzuje, že nižšie uvedený produkt spĺňa: nariadenia 2017/745, [vložit ďalšie príslušné právne predpisy EÚ] a vydáva sa s výhradnou zodpovednosťou výrobcu s registrovaným názvom
		3	Názov výrobcu
		4	Sídlo spoločnosti
		5	Jediné registračné číslo (SRN)
		6	Oprávnený zástupca pre EÚ
		7	Sídlo spoločnosti
		8	Názov produktu: (pozri priložený dodatok s kódmi výrobkov/katalógovými číslami)
		9	Plánované použitie: Ďalšie jazyky nájdete v tabuľke
		10	Postup posudzovania zhody (príloha)
		11	Názov notifikovaného orgánu
		12	Číslo notifikovaného orgánu
		13	Overovacie certifikáty
		14	Podpísaný v mene výrobcu s registrovaným názvom
		15	Podpis
		16	Meno
		17	Pozícia
		18	Dátum
		19	Miesto
		20	Odkaz na vyhlásenie o zhode
		21	Tabuľka výrobkov
		22	Kód výrobku / katalógové číslo
		23	Popis produktu alebo variant produktu
		24	Klasifikácia rizika
		25	Základný identifikátor UDI-DI
<b>Slovak:</b>	<b>SK</b>		

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	26	Normy / spoločné špecifikácie
	27	Číslo normy / spoločnej špecifikácie
	28	Plánované použitie prekladov z jazykov EÚ
	29	Jazyk

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Language <sup>29</sup>	Code	No.	Translated Terms
		1	EVROPSKA IZJAVA O SKLADNOSTI
		2	Izjava potrjuje, da spodaj navedeni izdelek ustreza: Uredbi 2017/745 [vstavite drugo zadevno evropsko zakonodajo, kakor je primerno], in je izdana na lastno odgovornost [Ime zakonitega proizvajalca]
		3	Ime proizvajalca
		4	Poslovni naslov
		5	Enotna registrska številka (SRN)
		6	Pooblaščen zastopnik za Evropo
		7	Poslovni naslov
		8	Ime izdelka: (glejte priložen dodatek s kodami/kataloškiimi številkami izdelkov)
		9	Predvidena uporaba: Za druge jezike glejte preglednico
		10	Postopek ugotavljanja skladnosti (Priloga)
		11	Ime priglašene organa
		12	Številka priglašene organa
		13	Potrdilo(-a) o verifikaciji
		14	Podpisano v imenu Ime zakonitega proizvajalca
		15	Podpis
		16	Ime
		17	Delovno mesto
		18	Datum
		19	Mesto
		20	Referenca Izjave o skladnosti
		21	Dodatek z izdelki
		22	Koda/kataloška številka izdelka
		23	Opis izdelka ali različica izdelka
		24	Razvrščanje v razred tveganja
		25	Osnovni UDI-DI
<b>Slovenian:</b>	<b>SL</b>		

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	26	Standardi/splošne specifikacije
	27	Standardna/splošna številka specifikacije
	28	Prevodi predvidene uporabe v evropske jezike
	29	Jezik

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Language <sup>29</sup>	Code	No.	Translated Terms
<b>Spanish:</b>	<b>ES</b>	1	DECLARACIÓN UE DE CONFORMIDAD
		2	Esta declaración confirma que el producto indicado a continuación cumple con lo estipulado en el Reglamento (UE) 2017/745, [incluir otras normativas europeas pertinentes que sean de aplicación] y se publica bajo la exclusiva responsabilidad de [Nombre legal del fabricante]
		3	Nombre del fabricante
		4	Domicilio social
		5	Número de registro único (SRN)
		6	Representante autorizado en Europa
		7	Domicilio social
		8	Nombre del producto: (véase el apéndice para comprobar los códigos/números de catálogo de los productos)
		9	Uso previsto: véase la tabla para consultar otros idiomas
		10	Procedimiento de evaluación de la conformidad (anexo)
		11	Nombre del organismo notificado
		12	Número del organismo notificado
		13	Certificados de verificación
		14	Firmado en nombre de [Nombre legal del fabricante]
		15	Firma
		16	Nombre
		17	Puesto
		18	Fecha
		19	Ubicación
		20	Referencia de la declaración de conformidad
		21	Apéndice del producto
		22	Código/número de catálogo del producto
		23	Descripción o variante del producto
		24	Clasificación del riesgo
		25	UDI-DI básica

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	26	Normas/especificaciones comunes
	27	Número de norma/especificación común
	28	Uso previsto: traducciones a idiomas europeos
	29	Idioma

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Language <sup>29</sup>	Code	No.	Translated Terms
<b>Swedish:</b>	<b>SE</b>	1	EUROPEISK FÖRSÄKRAN OM ÖVERENSSTÄMMELSE
		2	Denna försäkrans bekräftar att produkten som anges nedan uppfyller: kraven i förordning 2017/745, [infoga annan relevant Europeisk lagstiftning om tillämpligt] och utfärdas på eget ansvar av [tillverkarens namn]
		3	Tillverkarens namn
		4	Företagsadress
		5	Eudamed-registreringsnummer (SRN)
		6	Auktoriserad representant i Europa
		7	Företagsadress
		8	Produktnamn: (se den bifogade översikten för produktkoder/katalognummer)
		9	Avsedd användning: Se tabellen för andra språk
		10	Procedur för bedömning av överensstämmelse (bilaga)
		11	Anmälda organets namn
		12	Anmälda organets identifikationsnummer
		13	Verifieringscertifikat
		14	Undertecknat på [tillverkarens namn]:s vägnar
		15	Underskrift
		16	Namn
		17	Befattning
		18	Datum
		19	Placering
		20	Referens för försäkrans om överensstämmelse
		21	Produktöversikt
		22	Produktkod/katalognummer
		23	Produktbeskrivning eller produktvariant
		24	Riskklassificering
		25	Grundläggande UDI-DI

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	26	Standarder/gemensam (ma) specifikation(er)
	27	Standard/gemensamt specifikationsnummer
	28	Avsedd användning av översättningar till europeiska språk
	29	Språk

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**MANUFACTURER'S DECLARATION OF CONFORMITY**

*AUSTRALIAN THERAPEUTIC GOODS (MEDICAL DEVICES) REGULATIONS 2002*

**DECLARATION OF CONFORMITY PROCEDURES**

This is a declaration of conformity made under clause 6.6 of Schedule 3 to the Therapeutic Goods (Medical Devices) Regulations 2002.

**Manufacturer's name:** Smith & Nephew Medical Limited,  
**Business address:** 101 Hessle Road,  
Hull,  
HU3 2BN,  
United Kingdom.

**EU Authorised Representative:** Smith & Nephew Operations B.V.  
Bloemlaan 2,  
2132 NP Hoofddorp,  
Netherlands

**Medical device(s):** RENASYS Touch Canisters

**Classification:** Class I Non-Sterile  
**GMDN code and term:** 47404 – Negative-pressure wound therapy system canister

**Scope of application:** 66801273 – RENASYS Touch Canister with Solidifier 300ml  
66801274 – RENASYS Touch Canister with Solidifier 800ml  
66801275 – RENASYS Touch Canister without Solidifier 300ml

Each kind of medical device to which the technical documentation applies complies with the applicable provisions of the essential principles and the classification rules before being supplied.

**Verification Certificates** British Standards Institute. Certificate No. MD 76718 Quality Management System (EN ISO 13485)

**Standards applied:** EN ISO 13485:2016  
EN 60601-1:2005 3.1 edition  
EN 60601-1-11:2015 2<sup>nd</sup> edition  
EN ISO 14971:2019  
EN 62366-1:2015  
EN ISO 780:2015  
EN ISO 10993-1:2018  
EN ISO 20417:2021  
EN ISO 14644-1:2015

**Authorised signatory:**

**Name :** Ken Fergusson  
**Position :** Senior Regulatory Affairs Manager  
**Dated:** 07-Apr-2022 | 17:58:33 BST

DocuSigned by:  
  
 Signer Name: Ken Fergusson  
Signing Reason: I approve this document  
Signing Time: 07-Apr-2022 | 17:57:57 BST  
70CA089D3CF744E288FB372950E2A83E

**Certificate Reference** TGA/005 issue 02

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## EUROPEAN DECLARATION OF CONFORMITY <sup>1</sup>

Declaration confirms that the product listed below meets: Regulations 2017/745 and is issued under the sole responsibility of Smith & Nephew Medical Limited.<sup>2</sup>.

<b>Manufacturer's Name<sup>3</sup></b>	Smith & Nephew Medical Limited
<b>Business Address<sup>4</sup></b>	101 Hessle Road, Hull, HU3 2BN, United Kingdom
<b>Single Registration Number (SRN) <sup>5</sup></b>	GB-MF-000017580
<b>European Authorised Representative<sup>6</sup></b>	Smith & Nephew Operations B.V.
<b>Business Address<sup>7</sup></b>	Bloemlaan 2, 2132 NP Hoofddorp, Netherlands
<b>Product Name<sup>8</sup>:</b>	RENASYS Touch Carry Bag & Carry Strap RENASYS GO Carry Bag & Carry Strap
<b>Intended Use<sup>9</sup></b>	RENASYS GO and TOUCH Carry Bags & Carry Straps have no indications for use, however, they are intended to be used in conjunction with Smith & Nephew Negative Pressure Wound Therapy (NPWT) systems.
<b>Conformity Assessment Procedure (Annex)<sup>10</sup></b>	Not applicable, the devices are Class I Non-Sterile.
<b>Notified Body Name<sup>11</sup></b>	N/A
<b>Notified Body Number<sup>12</sup></b>	N/A
<b>Verification Certificate(s)<sup>13</sup></b>	N/A

<b>Signed on behalf of Smith &amp; Nephew Medical Limited <sup>14</sup></b>	
<b>Signature<sup>15</sup></b>	<p>DocuSigned by: <i>Sam Atkinson</i></p> <p> Signer Name: Sam Atkinson Signing Reason: I approve this document Signing Time: 14-Dec-2023   15:06:11 GMT 4247BB1FEDB542C29087D6B268F91213</p>
<b>Name<sup>16</sup></b>	Sam Atkinson
<b>Position<sup>17</sup></b>	Regulatory Approval Manager
<b>Date<sup>18</sup></b>	14-Dec-2023   15:06:43 GMT

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<b>Location<sup>19</sup></b>	Hull, UK
<b>Declaration of Conformity Reference<sup>20</sup></b>	DOC-WMTF-006/V2

<b>Product Schedule<sup>21</sup></b>			
<b>Product Code / Catalogue Number<sup>22</sup></b>	<b>Product Description or Product Variant<sup>23</sup></b>	<b>Risk Classification<sup>24</sup></b>	<b>Basic UDI<sup>25</sup></b>
66800162	RENASYS Go Carry Bag	Class I Non-Sterile	5000223SN000096RT
66800163	RENASYS Go Carry Strap	Class I Non-Sterile	5000223SN000096RT
66801276	RENASYS TOUCH Carry Strap	Class I Non-Sterile	5000223SN000096RT
66801277	RENASYS TOUCH Carry Bag	Class I Non-Sterile	5000223SN000096RT

<b>Standards / Common Specification(s)<sup>26</sup>:</b>			
EN ISO 780:2015	EN ISO 10993-1:2020		
EN ISO 13485:2016 +A1:2021	EN ISO 20417:2021		
EN ISO 15223-1:2021	EN 62366-1:2015 +A1:2020		
EN ISO 14971:2019 +A1:2021			

<b>Intended Use European Language Translations<sup>27</sup>:</b>			
<b>Language<sup>28</sup></b>		<b>Code</b>	<b>Intended Use</b>
<b>EN</b>	<b>Local</b>		
Bulgarian	български език	BG	Предназначени за употреба съвместно със системите за терапия на рани с отрицателно налягане (NPWT) на Smith & Nephew.
Croatian	Hrvatski	HR	Namijenjeno za upotrebu sa sustavima Smith & Nephew za liječenje rana negativnim tlakom.
Czech	Český Jazyk	CZ	Mělo by se využívat ve spojení se systémy podtlakové léčby ran (NPWT) společnosti Smith & Nephew.
Danish	Dansk	DK	Beregnet til at blive brugt sammen med Smith & Nephews systemer til sårbehandling med negativt tryk (NPWT).
Dutch	Nederlands	NL	Bedoeld voor gebruik in combinatie met systemen voor negatieve-drukwoondtherapie (NPWT-systemen) van Smith & Nephew.
Estonian	Eesti	EE	Mõeldud kasutamiseks koos Smith & Nephew alarõhuga haavaravisüsteemidega.

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Finnish	Suomi	FI	Tarkoitettu käytettäväksi yhdessä Smith & Nephew'n haavan alipaineimuhoidojärjestelmien (NPWT-järjestelmien) kanssa.
French	Français	FR	Destiné à être utilisé conjointement avec les systèmes de traitement des plaies par pression négative de Smith & Nephew (NPWT).
German	Deutsch	DE	Zur Verwendung gemeinsam mit den Smith & Nephew Unterdruck-Wundtherapie(NPWT)Systemen.
Greek	Ελληνικά	GR	Προορίζεται για χρήση σε συνδυασμό με τα συστήματα θεραπείας τραύματος με αρνητική πίεση (NPWT) της Smith & Nephew.
Hungarian	Magyar	HU	Használatra a Smith & Nephew negatív nyomású sebkezelési (Negative Pressure Wound Therapy, NPWT) rendszerekkel együtt javallott.
Italian	Italiano	IT	Previsto per l'uso con i sistemi di terapia a pressione negativa per il trattamento delle ferite (NPWT) di Smith & Nephew.
Latvian	Latviešu	LV	Paredzēts lietošanai kopā ar Smith & Nephew negatīvā spiediena brūču terapiju (negative pressure wound therapy jeb NPWT) sistēmām.
Lithuanian	Lietuvių	LT	Skirta naudoti kartu su „Smith & Nephew“ neigiamo slėgio žaizdų terapijos (angl. „Negative Pressure Wound Therapy“, NPWT) sistemomis.
Polish	Polski	PL	Przeznaczone do stosowania w połączeniu z systemami podciśnieniowego leczenia ran (NPWT) Smith & Nephew.
Portuguese	Português	PT	Destinam-se a ser utilizados com conjunto com sistemas de terapia de feridas por pressão negativa (TFPN) da Smith & Nephew.
Romanian	Română	RO	Este destinat utilizării în asociere cu sistemele de terapie cu presiune negativă pentru vindecarea plăgilor (NPWT) Smith & Nephew.
Slovak	Slovenčina	SK	Je určený na použitie spolu so systémami negatívnej tlakovej liečby rán Smith & Nephew (NPWT).
Slovenian	Slovenščina	SI	Predvideno za uporabo v povezavi s sistemi Smith & Nephew za zdravljenje ran z negativnim tlakom (NPWT).
Spanish	Español	ES	Indicado para utilizarse junto con los sistemas de terapia de heridas de presión negativa (TPN) de Smith & Nephew.
Swedish	Svenska	SE	Avsedd att användas tillsammans med Smith & Nephew:s system för sårbehandling med negativt tryck (NPWT).

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## Appendices - European Language Term Translations:

Appendix no.	Language (EN)	Language (Local)	Country Code
Appendix 1	Bulgarian	български език	BG
Appendix 2	Croatian	Hrvatski	HR
Appendix 3	Czech	Český Jazyk	CZ
Appendix 4	Danish	Dansk	DK
Appendix 5	Dutch	Nederlands	NL
Appendix 6	Estonian	Eesti	EE
Appendix 7	Finnish	Suomi	FI
Appendix 8	French	Français	FR
Appendix 9	German	Deutsch	DE
Appendix 10	Greek	Ελληνικά	GR
Appendix 11	Hungarian	Magyar	HU
Appendix 12	Italian	Italiano	IT
Appendix 13	Latvian	Latviešu	LV
Appendix 14	Lithuanian	Lietuvių	LT
Appendix 15	Polish	Polski	PL
Appendix 16	Portuguese	Português	PT
Appendix 17	Romanian	Română	RO
Appendix 18	Slovak	Slovenčina	SK
Appendix 19	Slovenian	Slovenščina	SL
Appendix 20	Spanish	Español	ES
Appendix 21	Swedish	Svenska	SE

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<b>Appendix 1</b>			
<b>Language (EN)</b>	Bulgarian (BG)	<b>Language (Local)</b>	български език
<b>No.</b>	<b>Translated Term</b>		
1	ЕВРОПЕЙСКА ДЕКЛАРАЦИЯ ЗА СЪОТВЕТСТВИЕ		
2	Декларацията потвърждава, че посоченият по-долу продукт съответства на: Регламент 2017/745, [въведете друго уместно европейско законодателство, според приложимото] и се издава единствено на отговорност на име на законния производител		
3	Име на производител		
4	Бизнес адрес		
5	Единен регистрационен номер (EPN)		
6	Упълномощен представител за Европа		
7	Бизнес адрес		
8	Име на продукт: (вижте приложения опис за продуктови кодове/каталожни номера)		
9	Предназначение: Вижте таблицата за други езици		
10	Процедура за оценяване на съответствието (Приложение)		
11	Име на нотифициран орган		
12	Номер на нотифициран орган		
13	Сертификат(и) за проверка		
14	Подписан от името на име на законния производител		
15	Подпис		
16	Име		
17	Длъжност		
18	Дата		
19	Местоположение		
20	Справка за декларация за съответствие		
21	Продуктов опис		
22	Продуктов код / Каталоген номер		
23	Описание на продукта или Вариант на продукта		
24	Класификация в зависимост от риска		
25	Основен уникален идентификатор на изделията - идентификатор на изделията		
26	Стандарти / Обща(и) спецификация(и)		
27	Предназначение: Преводи на европейски езици		
28	Език		

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Appendix 2			
Language (EN)	Croatian (HR)	Language (Local)	Hrvatski
No.	Translated Term		
1	EUROPSKA IZJAVA O SUKLADNOSTI		
2	Izjavom se potvrđuje da je niže navedeni proizvod u skladu s: Uredbama 2017/745, [unesite ostale mjerodavne Europske zakone, kako je primjenjivo]. Odgovornost za njeno izdavanje snosi isključivo [naziv proizvođača]		
3	Naziv proizvođača		
4	Adresa proizvođača		
5	Jedinstveni registracijski broj (SRN)		
6	Ovlašteni zastupnik za Europu		
7	Adresa ovlaštenog zastupnika		
8	Naziv proizvoda: (šifre proizvoda/kataloške brojeve potražite u priloženom dodatku)		
9	Namjena: Vidi tablicu za ostale jezike		
10	Postupak procjenjivanja sukladnosti (Prilog)		
11	Naziv prijavljenog tijela		
12	Broj prijavljenog tijela		
13	Potvrda (potvrde) o provjeri		
14	Potpisao/-la u ime [naziv proizvođača]		
15	Potpis		
16	Ime I prezime		
17	Funkcija		
18	Datum		
19	Mjesto		
20	Oznaka izjave o sukladnosti		
21	Dodatak za proizvod		
22	Šifra proizvoda / kataloški broj		
23	Opis proizvoda ili inačica proizvoda		
24	Klasa rizika		
25	Osnovna jedinstvena identifikacija proizvoda-identifikator proizvoda (UDI-DI)		
26	Norme / Uobičajena specifikacija (Uobičajene specifikacije)		
27	Namjena: prijevodi na europske jezike		
28	Jezik		

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Appendix 3			
Language (EN)	Czech (CZ)	Language (Local)	Český Jazyk
No.	Translated Term		
1	EVROPSKÉ PROHLÁŠENÍ O SHODĚ		
2	Prohlášení potvrzuje, že níže uvedený výrobek splňuje nařízení 2017/745 [případně doplňte další příslušné evropské právní předpisy], a je vydáno na výhradní zodpovědnost [oficiální název výrobce]		
3	Název výrobce		
4	Adresa místa podnikání		
5	Jediné registrační číslo		
6	Oprávněný zástupce pro Evropu		
7	Adresa místa podnikání		
8	Název výrobku: (kód výrobku / katalogové číslo viz příložený soupis)		
9	Určené použití: Viz tabulka pro další jazyky		
10	Postup posuzování shody (příloha)		
11	Název oznámeného subjektu		
12	Číslo oznámeného subjektu		
13	Osvědčení o ověření		
14	Podepsáno jménem [oficiální název výrobce]		
15	Podpis		
16	Jméno		
17	Pozice		
18	Datum		
19	Místo		
20	Prohlášení o shodě – reference		
21	Soupis výrobků		
22	Kód výrobku / katalogové číslo		
23	Popis výrobku nebo varianta výrobku		
24	Klasifikace rizik		
25	Základní UDI-DI		
26	Normy / společné specifikace		
27	Zamýšlené použití: překlad do evropských jazyků		
28	Jazyk		

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Appendix 4				
Language (EN)		Danish (DK)	Language (Local)	Dansk
No.	Translated Term			
1	EUROPÆISK OVERENSSTEMMELSESERKLÆRING			
2	Erklæringen bekræfter, at produkterne angivet herunder overholder: Forordning 2017/745, [indsæt anden gældende europæisk lovgivning hvis relevant] og er udstedt med eneansvar for [Juridisk fabrikantnavn]			
3	Fabrikantens navn			
4	Virksomhedsadresse			
5	Individuelt registreringsnummer (Single Registration Number, SRN)			
6	Autoriseret europæisk repræsentant			
7	Virksomhedsadresse			
8	Produktnavn: (se vedlagte bilag for produktkoder/katalognumre)			
9	Tilsiptet brug: Se tabel for andre sprog			
10	Procedure for overensstemmelsesvurdering (bilag)			
11	Bemyndiget organ, navn			
12	Bemyndiget organ, nummer			
13	Verifikationscertifikat(er)			
14	Underskrevet på vegne af [Juridisk fabrikantnavn]			
15	Underskrift			
16	Navn			
17	Position			
18	Dato			
19	Placering			
20	Overensstemmelseserklæring, reference			
21	Produktbilag			
22	Produktkode/katalognummer			
23	Produktbeskrivelse eller produktvariant			
24	Risikoklasse			
25	Grundlæggende UDI-DI			
26	Standarder/almindelig(e) specifikation(er)			
27	Tilsiptet brug: Oversættelser på europæiske sprog			
28	Sprog			

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Appendix 5				
Language (EN)		Dutch (NL)	Language (Local)	Nederlands
No.	Translated Term			
1	EUROPESE CONFORMITEITSVERKLARING			
2	Deze verklaring bevestigt dat het hieronder vermelde product voldoet aan: Verordening 2017/745, [andere relevante Europese wetgeving invoegen indien van toepassing] en wordt uitgegeven onder de uitsluitende verantwoordelijkheid van [wettige naam van fabrikant]			
3	Naam van de fabrikant			
4	Bedrijfsadres			
5	SRN (single registration number: uniek registratienummer)			
6	Geautoriseerde vertegenwoordiger voor Europa			
7	Bedrijfsadres			
8	Productnaam: (zie bijgevoegd bijlage voor productcodes/catalogusnummers)			
9	Beoogd gebruik: Zie de tabel voor andere Europese talen			
10	Conformiteitsbeoordelingsprocedure (bijlage)			
11	Naam van aangemelde instantie			
12	Nummer van aangemelde instantie			
13	Verificatiecertificaat/-certificaten			
14	Ondertekend namens [naam van de fabrikant]			
15	Handtekening			
16	Naam			
17	Functie			
18	Datum			
19	Plaats			
20	Referentie conformiteitsverklaring			
21	Productschema			
22	Productcode/catalogusnummer			
23	Productbeschrijving of productvariant			
24	Risicoclassificatie			
25	Basis UDI-DI			
26	Standaarden/Algemene specificatie(s)			
27	Beoogd gebruik: vertalingen in Europese talen			
28	Taal			

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Appendix 6			
Language (EN)	Estonian (EE)	Language (Local)	Eesti
No.	Translated Term		
1	EUROOPA VASTAVUSDEKLARATSIOON		
2	Selle deklaratsiooniga kinnitame allpool loetletud toote vastavust: määrusele 2017/745 [sisestage muu Euroopa õigusakt, kui on kohaldatav] ning see väljastatakse [seadusliku tootja nimi] ainuvastutusel		
3	Tootja nimi		
4	Registreeritud aadress		
5	Unikaalne registreerimisnumber (SRN)		
6	Volitatud esindaja Euroopas		
7	Registreeritud aadress		
8	Toote nimetus: (tootekood/katalooginumbreid vt lisatud tabelist)		
9	Ettenähtud kasutusotstarve: Teisi keeli vt tabelist		
10	Vastavushindamise protseduur (lisa)		
11	Teavitatud asutuse nimetus		
12	Teavitatud asutuse number		
13	Kinnitussertifikaat/-sertifikaadid		
14	Allkirjastanud [seadusliku tootja nimi]		
15	Allkiri		
16	Nimi		
17	Ametikoht		
18	Kuupäev		
19	Asukoht		
20	Vastavusdeklaratsiooni viide		
21	Toote tabel		
22	Tootekood/katalooginumber		
23	Toote kirjeldus või toote variant		
24	Riski klassifikatsioon		
25	Põhiline UDI-DI		
26	Standardid / ühtsed tehnilised tingimused		
27	Ettenähtud kasutusotstarve Tõlked Euroopa keeltesse		
28	Keel		

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Appendix 7			
Language (EN)		Finnish (FI)	Language (Local)
			Suomi
No.	Translated Term		
1	EUROOPPALAINEN VAATIMUSTENMUKAISUUSVAKUUTUS		
2	Vakuutuksella vahvistetaan, että jäljempänä mainittu tuote täyttää: Asetuksen 2017/745, [tähän tulee lisätä muu asiaan liittyvä eurooppalainen lainsäädäntö sikäli kuin sitä on] mukaiset vaatimukset, ja annetusta vakuutuksesta vastuussa on yksinomaan [laillisen valmistajan nimi]		
3	Valmistajan nimi		
4	Toimipaikan osoite		
5	Rekisterinumero (SRN)		
6	Eurooppalainen valtuutettu edustaja		
7	Toimipaikan osoite		
8	Tuotteen nimi: (ks. liitteestä tuotekoodit/luettelonumerot)		
9	Käyttötarkoitus: Taulukossa esitetään muut kieliversiot		
10	Vaatimustenmukaisuuden arviointimenettely (Liite)		
11	Ilmoitetun laitoksen nimi		
12	Ilmoitetun laitoksen numero		
13	Tarkastustodistus (-todistukset)		
14	Allekirjoitettu puolesta [laillisen valmistajan nimi]		
15	Allekirjoitus		
16	Nimi		
17	Asema		
18	Päiväys		
19	Paikka		
20	Vaatimustenmukaisuusvakuutuksen viite		
21	Tuoteluettelo		
22	Tuotekoodi / Luettelonumero		
23	Tuotekuvaus tai tuotevariantti		
24	Riskiluokitus		
25	Perus-UDI-DI-tunniste		
26	Standardit / Yhteinen eritelmä (tai monikossa)		
27	Käyttötarkoitus Käännökset Euroopan kielillä		
28	Kieli		

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<b>Appendix 8</b>			
<b>Language (EN)</b>		<b>Language (Local)</b>	
French (FR)		Français	
<b>No.</b>	<b>Translated Term</b>		
1	DÉCLARATION DE CONFORMITÉ EU		
2	La déclaration confirme que le produit repris ci-dessous est conforme au : Règlement (UE) 2017/745 [insérer au besoin toute autre législation européenne pertinente] et est publiée sous la seule responsabilité de Nom du fabricant légal		
3	Nom du fabricant		
4	Adresse professionnelle		
5	Numéro d'enregistrement unique		
6	Mandataire établi dans l'UE		
7	Adresse professionnelle		
8	Nom du produit : (voir l'annexe jointe pour les codes de produit/références catalogue)		
9	Usage prévu : Voir le tableau pour les autres langues		
10	Procédure d'évaluation de la conformité (Annexe)		
11	Nom de l'organisme notifié		
12	N° de l'organisme notifié		
13	Certificat(s) de vérification		
14	Signé au nom de Nom du fabricant légal		
15	Signature		
16	Nom		
17	Fonction du signataire		
18	Date		
19	Adresse		
20	Référence de la déclaration de conformité		
21	Information produit		
22	Code du produit / Référence catalogue du produit		
23	Description du produit ou variante du produit		
24	Classe de risque		
25	Identifiant « dispositif » IUD (IUD-ID)		
26	Normes / Spécification(s) commune(s)		
27	Usage prévu : traduction dans les langues européennes		
28	Langue		

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<b>Appendix 9</b>				
<b>Language (EN)</b>		German (DE)	<b>Language (Local)</b>	Deutsch
<b>No.</b>	<b>Translated Term</b>			
1	EUROPÄISCHE KONFORMITÄTSERKLÄRUNG			
2	Mit dieser Erklärung wird bestätigt, dass das unten aufgeführte Produkt den folgenden Anforderungen entspricht: Verordnungen 2017/745, [ggf. andere einschlägige europäische Rechtsvorschriften einfügen]. Die alleinige Verantwortung für die Ausstellung dieser Konformitätserklärung trägt [Name des Herstellers]			
3	Name des Herstellers			
4	Geschäftsadresse			
5	Einmalige Registrierungsnummer (SRN)			
6	Europäischer Bevollmächtigter			
7	Geschäftsadresse			
8	Produktname: (Produktcodes/Katalognummern siehe beigefügtes Verzeichnis)			
9	Verwendungszweck: Andere Sprachen siehe Tabelle			
10	Konformitätsbewertungsverfahren (Anhang)			
11	Name der benannten Stelle			
12	Nummer der benannten Stelle			
13	Prüfzertifikat(e)			
14	Unterschrift im Auftrag von Name des Herstellers			
15	Unterschrift			
16	Name			
17	Position			
18	Datum			
19	Standort			
20	Konformitätserklärung – Referenz			
21	Produktverzeichnis			
22	Produktcode/Katalognummer			
23	Produktbeschreibung oder Produktvariante			
24	Risikoklassifizierung			
25	Basis-UDI-DI			
26	Normen/Gemeinsame Spezifikation(en)			
27	Verwendungszweck: Übersetzung in europäische Sprachen			
28	Sprache			

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Appendix 10			
Language (EN)	Greek (GR)	Language (Local)	Ελληνικά
No.	Translated Term		
1	ΕΥΡΩΠΑΪΚΗ ΔΗΛΩΣΗ ΣΥΜΜΟΡΦΩΣΗΣ		
2	Η δήλωση επιβεβαιώνει ότι το προϊόν που αναφέρεται παρακάτω πληροί: τους κανονισμούς 2017/745, [συμπληρώστε άλλη σχετική ευρωπαϊκή νομοθεσία ανάλογα με την περίπτωση] και εκδίδεται υπό την αποκλειστική ευθύνη του [επωνυμία νόμιμου κατασκευαστή]		
3	Επωνυμία κατασκευαστή		
4	Διεύθυνση επιχείρησης		
5	Ενιαίος αριθμός καταχώρισης (SRN)		
6	Εξουσιοδοτημένος αντιπρόσωπος στην Ευρώπη		
7	Διεύθυνση επιχείρησης		
8	Ονομασία προϊόντος: (βλ. συνημμένο παράρτημα κωδικών προϊόντων/αριθμών καταλόγου)		
9	Προβλεπόμενη χρήση: βλ. πίνακα για άλλες γλώσσες		
10	Διαδικασία εκτίμησης της συμμόρφωσης (παράρτημα)		
11	Επωνυμία κοινοποιημένου οργανισμού		
12	Αριθμός κοινοποιημένου οργανισμού		
13	Πιστοποιητικό(ά) επαλήθευσης		
14	Υπογραφή εξ ονόματος του [επωνυμία νόμιμου κατασκευαστή]		
15	Υπογραφή		
16	Ονοματεπώνυμο		
17	Τίτλος		
18	Ημερομηνία		
19	Τοποθεσία		
20	Αναφορά δήλωσης συμμόρφωσης		
21	Παράρτημα προϊόντων		
22	Κωδικός προϊόντος/Αριθμός καταλόγου		
23	Περιγραφή προϊόντος ή παραλλαγή προϊόντος		
24	Ταξινόμηση κινδύνου		
25	Βασικό UDI-DI		
26	Πρότυπα/Κοινή(ές) προδιαγραφή(ές)		
27	Προβλεπόμενη χρήση: μεταφράσεις σε ευρωπαϊκές γλώσσες		
28	Γλώσσα		

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<b>Appendix 11</b>			
<b>Language (EN)</b>	Hungarian (HU)	<b>Language (Local)</b>	Magyar
<b>No.</b>	<b>Translated Term</b>		
1	EURÓPAI MEGFELELŐSÉGI NYILATKOZAT		
2	A nyilatkozat megerősíti, hogy az alább felsorolt termék megfelel a következőknek: A 2017/745 rendeletek, [értelemszerűen illessze be ide az egyéb fontos európai jogszabályokat], és kiadása a [gyártó hivatalos neve] kizárólagos felelősségére történik		
3	A gyártó neve		
4	Székhelye		
5	Egyedi nyilvántartási szám (SRN)		
6	Meghatalmazott európai képviselő		
7	Székhelye		
8	A termék neve: (lásd a mellékelt listát a termékkódokat/katalógusszámokat illetően)		
9	Rendeltetésszerű használat: Az egyéb nyelveket lásd a táblázatban		
10	Megfelelőségértékelési eljárás (melléklet)		
11	Kijelölt szervezet neve		
12	Kijelölt szervezet száma		
13	Hitelesítési tanúsítvány(ok)		
14	Aláírva a [gyártó hivatalos neve] nevében		
15	Aláírás		
16	Név		
17	Beosztás		
18	Dátum		
19	Hely		
20	A megfelelőségi nyilatkozat hivatkozása		
21	Terméklista		
22	Termékkód/katalógusszám		
23	A termék leírása vagy termékváltozat		
24	Kockázatbesorolás		
25	Alap UDI-DI		
26	Szabványok / általános specifikáció(k)		
27	A rendeltetésszerű használat európai nyelvre történt fordítása		
28	Nyelv		

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<b>Appendix 12</b>				
<b>Language (EN)</b>		Italian (IT)	<b>Language (Local)</b>	
			Italiano	
<b>No.</b>	<b>Translated Term</b>			
1	DICHIARAZIONE DI CONFORMITÀ EUROPEA			
2	La dichiarazione conferma che il prodotto menzionato di seguito è conforme a: Regolamento 2017/745, [inserire altre normative europee pertinenti per quanto applicabile], ed è rilasciata sotto l'esclusiva responsabilità del fabbricante legale			
3	Nome del fabbricante			
4	Indirizzo aziendale			
5	Numero di registrazione unico (Single Registration Number, SRN)			
6	Rappresentante europeo autorizzato			
7	Indirizzo aziendale			
8	Nome del prodotto: (vedere il prospetto allegato per i codici di prodotto/numeri di catalogo)			
9	Uso previsto: vedere la tabella per le altre lingue			
10	Procedura di valutazione di conformità (Allegato)			
11	Nome dell'organismo notificato			
12	Numero dell'organismo notificato			
13	Certificazione/i di verifica			
14	Firmato in nome e per conto di (nome del fabbricante legale)			
15	Firma			
16	Nome			
17	Posizione professionale			
18	Data			
19	Sede			
20	Riferimento per la Dichiarazione di conformità			
21	Prospetto prodotti			
22	Codice prodotto/Numero di catalogo			
23	Descrizione del prodotto o variante di prodotto			
24	Classificazione del rischio			
25	Codice UDI-DI			
26	Norme/Specifiche comuni			
27	Uso previsto: traduzioni nelle lingue europee			
28	Lingua			

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<b>Appendix 13</b>			
<b>Language (EN)</b>		Latvian (LV)	<b>Language (Local)</b>
			Latviešu
<b>No.</b>	<b>Translated Term</b>		
1	EIROPAS ATBILSTĪBAS DEKLARĀCIJA		
2	Deklarācija apliecina, ka tālāk norādītais produkts atbilst: Regulām 2017/745, [ievietojiet citus atbilstošus Eiropas tiesību aktus, kā nepieciešams], un tā ir izsniegta tikai uz [ražotāja juridiskais nosaukums] atbildību		
3	Ražotāja nosaukums		
4	Uzņēmuma adrese		
5	Vienotais reģistrācijas numurs (VRN)		
6	Pilnvarotais pārstāvis Eiropā		
7	Uzņēmuma adrese		
8	Produkta nosaukums: (produkta kodus/kataloga numurus skatīt pievienotajā pielikumā)		
9	Paredzētā lietošana: informāciju par citām valodām skatīt tabulā		
10	Atbilstības novērtēšanas procedūra (Pielikums)		
11	Paziņotās struktūras nosaukums		
12	Paziņotās struktūras numurs		
13	Pārbaudes sertifikāts(-i)		
14	Parakstīts [ražotāja juridiskais nosaukums] vārdā		
15	Paraksts		
16	Vārds, uzvārds		
17	Amats		
18	Datums		
19	Vieta		
20	Atbilstības deklarācijas atsauce		
21	Produkta pielikums		
22	Produkta kods/kataloga numurs		
23	Produkta apraksts vai produkta variants		
24	Riska klasifikācija		
25	Pamata UDI-DI		
26	Standarti/vispārīgā(-s) specifikācija(-s)		
27	Paredzētā lietošana: tulkojumi Eiropas valodās		
28	Valoda		

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Appendix 14			
Language (EN)	Lithuanian (LT)	Language (Local)	Lietuvių
No.	Translated Term		
1	Europos Atitikties Deklaracija		
2	Delaracija patvirtina kad toliau išvardyti produktai atitinka: Reglamentą 2017/745, [[terpti kitus taikytinus Europos teisės aktus] ir už jo išdavimą yra visiškai atsakingas [legalus gamintojo vardas].		
3	Gamintojo pavadinimas		
4	Verslo adresas		
5	Bendras Registracijos Numeris (BRN)		
6	Europos įgaliotasis atstovas		
7	Verslo adresas		
8	Produkto vardas: (produktų kodus / katalogo numerius žiūrėkite priede)		
9	Paskirtis: kitomis kalbomis žiūrėkite lentelę		
10	Atitikties deklaracija (priedas)		
11	Notifikuotosios įstaigos pavadinimas		
12	Notifikuotosios įstaigos numeris		
13	Patvirtinimo sertifikatas (-ai)		
14	Pasirašyta (legalaus gamintojo vardas) vardu		
15	Parašas		
16	Vardas		
17	Pareigos		
18	Data		
19	Vieta		
20	Atitikties Deklaracijos Nuoroda		
21	Produktų sąrašas		
22	Produkto Kodas/ Katalogo numeris		
23	Produkto Apibūdinimas arba Produkto Variantas		
24	Rizikos Klasifikacija		
25	Pagrindinis UDI		
26	Standartai / Bendroji specifikacija (-os)		
27	Numatomi vartoti Europos šalių kalbų vertimai		
28	Kalba		

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<b>Appendix 15</b>			
<b>Language (EN)</b>		<b>Language (Local)</b>	
Polish (PL)		Polski	
<b>No.</b>	<b>Translated Term</b>		
1	EUROPEJSKA DEKLARACJA ZGODNOŚCI		
2	Deklaracja potwierdza, że wymieniony poniżej produkt spełnia wymagania: Rozporządzenia 2017/745 [w razie potrzeby wstawić inne stosowne przepisy europejskie] i jest wydawana na wyłączną odpowiedzialność Nazwa producenta		
3	Nazwa producenta		
4	Adres firmy		
5	Niepowtarzalny numer rejestracyjny (SRN)		
6	Upoważniony przedstawiciel w Unii Europejskiej		
7	Adres firmy		
8	Nazwa produktu: (kody produktów / numery katalogowe zawiera załączony wykaz)		
9	Przewidziane używanie : Tekst w innych językach znajduje się w tabeli		
10	Procedura oceny zgodności (załącznik)		
11	Nazwa jednostki notyfikowanej		
12	Numer jednostki notyfikowanej		
13	Certyfikaty weryfikacji		
14	Podpisano w imieniu Nazwa producenta		
15	Podpis		
16	Imię i nazwisko		
17	Stanowisko		
18	Data		
19	Miejsce		
20	Numer referencyjny deklaracji zgodności		
21	Wykaz produktów		
22	Kod produktu / numer katalogowy		
23	Opis produktu lub wariant produktu		
24	Klasyfikacja ryzyka		
25	Kod Basic UDI-DI		
26	Normy / wspólne specyfikacje		
27	Tłumaczenia tekstu dotyczącego przeznaczenia produktu na języki europejskie		
28	Język		

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Appendix 16				
Language (EN)		Portuguese (PT)	Language (Local)	Português
No.	Translated Term			
1	DECLARAÇÃO DE CONFORMIDADE EUROPEIA			
2	A declaração confirma que os produtos listados abaixo cumprem: Regulamentação 2017/745, [inserir outra legislação europeia relevante, conforme aplicável] e é emitida sob a responsabilidade única do [Nome legal do fabricante]			
3	Nome do fabricante			
4	Endereço da empresa			
5	Número único de registo (NUR)			
6	Representante Europeu Autorizado			
7	Endereço da empresa			
8	Nome do produto: (consulte o anexo quanto a códigos de produtos/números de catálogo)			
9	Finalidade: Consulte a tabela para outros idiomas			
10	Procedimento de avaliação de conformidade (Anexo)			
11	Nome do organismo notificado			
12	Número do organismo notificado			
13	Certificado(s) de verificação			
14	Assinado em nome de [Nome legal do fabricante]			
15	Assinatura			
16	Nome			
17	Cargo			
18	Data			
19	Localização			
20	Referência de Declaração de conformidade			
21	Anexo do produto			
22	Código de produto / Número de catálogo			
23	Descrição do produto ou variante do produto			
24	Classificação de risco			
25	UDI-DI básico			
26	Normas / Especificação(ões) comum(ns)			
27	Traduções da Finalidade para idiomas europeus			
28	Idioma			

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<b>Appendix 17</b>			
<b>Language (EN)</b>		Romanian (RO)	<b>Language (Local)</b>
			Română
<b>No.</b>	<b>Translated Term</b>		
1	DECLARAȚIE DE CONFORMITATE EUROPEANĂ		
2	Declarația confirmă faptul că produsul specificat mai jos respectă: Regulamentul 2017/745, [introduceți ale acte legislative europene relevante, după caz] și este emis pe propria răspundere a Denumirea juridică a producătorului		
3	Denumirea producătorului		
4	Sediul social		
5	Număr unic de înregistrare (CUI)		
6	Reprezentant european autorizat		
7	Sediul social		
8	Denumirea produsului: (consultați anexa atașată pentru codurile de produs/numerele de catalog)		
9	Utilizare preconizată: consultați tabelul pentru alte limbi		
10	Procedura de evaluare a conformității (Anexă)		
11	Denumirea organismului notificat		
12	Numărul organismului notificat		
13	Certificat(e) de verificare		
14	Semnat în numele Denumirea juridică a producătorului		
15	Semnătură		
16	Nume		
17	Funcție		
18	Dată		
19	Locație		
20	Referință pentru declarația de conformitate		
21	Anexa produsului		
22	Cod produs / Număr de catalog		
23	Descrierea produsului sau varianta produsului		
24	Clasificarea riscurilor		
25	UDI-DI (identificator unic de dispozitiv) de bază		
26	Standarde / Specificație(i) comună(e)		
27	Utilizare preconizată: traduceri în limbile europene		
28	Limbă		

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<b>Appendix 18</b>			
<b>Language (EN)</b>	Slovak (SK)	<b>Language (Local)</b>	Slovenčina
<b>No.</b>	<b>Translated Term</b>		
1	VYHLÁSENIE O ZHODE EÚ		
2	Vyhlásenie potvrdzuje, že nižšie uvedený produkt spĺňa: nariadenia 2017/745, [vložiť ďalšie príslušné právne predpisy EÚ] a vydáva sa s výhradnou zodpovednosťou výrobcu s registrovaným názvom		
3	Názov výrobcu		
4	Sídlo spoločnosti		
5	Jediné registračné číslo (SRN)		
6	Oprávnený zástupca pre EÚ		
7	Sídlo spoločnosti		
8	Názov produktu: (pozri priložený dodatok s kódmi výrobkov/katalógovými číslami)		
9	Plánované použitie: Ďalšie jazyky nájdete v tabuľke		
10	Postup posudzovania zhody (príloha)		
11	Názov notifikovaného orgánu		
12	Číslo notifikovaného orgánu		
13	Overovacie certifikáty		
14	Podpísaný v mene výrobcu s registrovaným názvom		
15	Podpis		
16	Meno		
17	Pozícia		
18	Dátum		
19	Miesto		
20	Odkaz na vyhlásenie o zhode		
21	Tabuľka výrobkov		
22	Kód výrobku / katalógové číslo		
23	Popis produktu alebo variant produktu		
24	Klasifikácia rizika		
25	Základný identifikátor UDI-DI		
26	Normy / spoločné špecifikácie		
27	Plánované použitie prekladov z jazykov EÚ		
28	Jazyk		

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Appendix 19			
Language (EN)	Slovenian (SI)	Language (Local)	Slovenščina
No.	Translated Term		
1	EVROPSKA IZJAVA O SKLADNOSTI		
2	Izjava potrjuje, da spodaj navedeni izdelek ustreza: Uredbi 2017/745 [vstavite drugo zadevno evropsko zakonodajo, kakor je primerno], in je izdana na lastno odgovornost [Ime zakonitega proizvajalca]		
3	Ime proizvajalca		
4	Poslovni naslov		
5	Enotna registrska številka (SRN)		
6	Pooblaščen zastopnik za Evropo		
7	Poslovni naslov		
8	Ime izdelka: (glejte priložen dodatek s kodami/kataloškiimi številkami izdelkov)		
9	Predvidena uporaba: Za druge jezike glejte preglednico		
10	Postopek ugotavljanja skladnosti (Priloga)		
11	Ime priglašenega organa		
12	Številka priglašenega organa		
13	Potrdilo(-a) o verifikaciji		
14	Podpisano v imenu Ime zakonitega proizvajalca		
15	Podpis		
16	Ime		
17	Delovno mesto		
18	Datum		
19	Kraj		
20	Referenca Izjave o skladnosti		
21	Dodatek z izdelki		
22	Koda/kataloška številka izdelka		
23	Opis izdelka ali različica izdelka		
24	Razvrščanje v razred tveganja		
25	Osnovni UDI-DI		
26	Standardi/splošne specifikacije		
27	Prevodi predvidene uporabe v evropske jezike		
28	Jezik		

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<b>Appendix 20</b>			
<b>Language (EN)</b>		<b>Language (Local)</b>	
Spanish (ES)		Español	
<b>No.</b>	<b>Translated Term</b>		
1	DECLARACIÓN UE DE CONFORMIDAD		
2	Esta declaración confirma que el producto indicado a continuación cumple con lo estipulado en el Reglamento (UE) 2017/745, [incluir otras normativas europeas pertinentes que sean de aplicación] y se publica bajo la exclusiva responsabilidad de [Nombre legal del fabricante]		
3	Nombre del fabricante		
4	Domicilio social		
5	Número de registro único (SRN)		
6	Representante autorizado en Europa		
7	Domicilio social		
8	Nombre del producto: (véase el apéndice para comprobar los códigos/números de catálogo de los productos)		
9	Uso previsto: véase la tabla para consultar otros idiomas		
10	Procedimiento de evaluación de la conformidad (anexo)		
11	Nombre del organismo notificado		
12	Número del organismo notificado		
13	Certificados de verificación		
14	Firmado en nombre de [Nombre legal del fabricante]		
15	Firma		
16	Nombre		
17	Puesto		
18	Fecha		
19	Ubicación		
20	Referencia de la declaración de conformidad		
21	Apéndice del producto		
22	Código/número de catálogo del producto		
23	Descripción o variante del producto		
24	Clasificación del riesgo		
25	UDI-DI básica		
26	Normas/especificaciones comunes		
27	Uso previsto: traducciones a idiomas europeos		
28	Idioma		

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<b>Appendix 21</b>			
<b>Language (EN)</b>	Swedish (SE)	<b>Language (Local)</b>	Svenska
<b>No.</b>	<b>Translated Term</b>		
1	EUROPEISK FÖRSÄKRAN OM ÖVERENSSTÄMMELSE		
2	Denna försäkran bekräftar att produkten som anges nedan uppfyller: kraven i förordning 2017/745, [infoga annan relevant Europeisk lagstiftning om tillämpligt] och utfärdas på eget ansvar av [tillverkarens namn]		
3	Tillverkarens namn		
4	Företagsadress		
5	Eudamed-registreringsnummer (SRN)		
6	Auktoriserad representant i Europa		
7	Företagsadress		
8	Produktnamn: (se den bifogade översikten för produktkoder/katalognummer)		
9	Avsedd användning: Se tabellen för andra språk		
10	Procedur för bedömning av överensstämmelse (bilaga)		
11	Anmälda organets namn		
12	Anmälda organets identifikationsnummer		
13	Verifieringscertifikat		
14	Undertecknat på [tillverkarens namn]:s vägnar		
15	Underskrift		
16	Namn		
17	Befattning		
18	Datum		
19	Placering		
20	Referens för försäkran om överensstämmelse		
21	Produktöversikt		
22	Produktkod/katalognummer		
23	Produktbeskrivning eller produktvariant		
24	Riskklassificering		
25	Grundläggande UDI-DI		
26	Standarder/gemensam(ma) specifikation(er)		
27	Avsedd användning av översättningar till europeiska språk		
28	Språk		

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## EUROPEAN DECLARATION OF CONFORMITY <sup>1</sup>

Declaration confirms that the product listed below meets: Regulations 2017/745 and is issued under the sole responsibility of Smith & Nephew Medical Limited<sup>2</sup>.

<b>Manufacturer's Name<sup>3</sup></b>	Smith & Nephew Medical Limited
<b>Business Address<sup>4</sup></b>	101 Hessle Road, Hull, HU3 2BN, United Kingdom
<b>Single Registration Number (SRN) <sup>5</sup></b>	GB-MF-000017580
<b>European Authorised Representative<sup>6</sup></b>	Smith & Nephew Operations B.V.
<b>Business Address<sup>7</sup></b>	Bloemlaan 2, 2132 NP Hoofddorp, Netherlands
<b>Product Name<sup>8</sup>:</b>	RENASYS-F Foam Dressing Kit with Soft Port Foam Wound Dressing RENASYS Transparent Film Dressing RENASYS Soft Port
<b>Intended Use<sup>9</sup></b>	The RENASYS NPWT System is indicated for patients who would benefit from a suction pump (Negative Pressure Wound Therapy), as it may promote wound healing via the removal of fluids, including irrigation and body fluids, wound exudate and infectious materials. Appropriate wound types include: Chronic, Acute, Traumatic, Sub-Acute and dehisced wounds, Ulcers (such as pressure or diabetic), Partial-thickness burns, Flaps, Grafts
<b>Conformity Assessment Procedure (Annex)<sup>10</sup></b>	ANNEX IX
<b>Notified Body Name<sup>11</sup></b>	BSI Group The Netherlands B.V
<b>Notified Body Number<sup>12</sup></b>	No. 2797
<b>Verification Certificate(s)<sup>13</sup></b>	MDR 732832

<b>Signed on behalf of Smith &amp; Nephew Medical Limited<sup>14</sup></b>	
<b>Signature<sup>15</sup></b>	<p>DocuSigned by:                   Signer Name: sam greenhalgh                  Signing Reason: I approve this document                  Signing Time: 25-Jul-2024   10:11:25 BST                  1C73ED93193D48889F66F071859C80BC</p>

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<b>Name<sup>16</sup></b>	Sam Greenhalgh
<b>Position<sup>17</sup></b>	Regulatory Affairs Director
<b>Date<sup>18</sup></b>	25-Jul-2024   10:11:53 BST
<b>Location<sup>19</sup></b>	Hull, United Kingdom
<b>Declaration of Conformity Reference<sup>20</sup></b>	EU DOC-WMTF-073_Rev 02

Product Schedule <sup>21</sup>				
Product Code / Catalogue Number <sup>22</sup>	Product Description or Product Variant <sup>23</sup>		Risk Classification <sup>24</sup>	Basic UDI <sup>25</sup>
66800794	RENASYS-F Foam Dressing Kit with Soft Port - Small Kit	1x Foam Wound Dressing (10cmx8cmx3cm) 1x RENASYS Transparent Film Dressing (20x30cm) 1x RENASYS Soft Port	Class IIb	5000223SN000172RJ
66800795	RENASYS-F Foam Dressing Kit with Soft Port - Medium Kit	1x Foam Wound Dressing (20cmx12.5cmx3cm) 2x RENASYS Transparent Film Dressings (20x30cm) 1x RENASYS Soft Port	Class IIb	5000223SN000172RJ
66800796	RENASYS-F Foam Dressing Kit with Soft Port - Large Kit	1x Foam Wound Dressing (25cmx15cmx3cm) 3x RENASYS Transparent Film Dressings (20x30cm) 1x RENASYS Soft Port	Class IIb	5000223SN000172RJ
66800797	RENASYS-F Foam Dressing Kit with Soft Port - X-Large Kit	1x Foam Wound Dressing (48cmx41cmx1.5cm) 6x RENASYS Transparent Film Dressings (20x30cm) 1x RENASYS Soft Port	Class IIb	5000223SN000172RJ

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66801021	Foam Wound Dressing	10x12.5cm, Single	Class IIb	5000223SN000166RP
66800394	RENASYS Transparent Film Dressing Negative Pressure Wound Therapy (NPWT)	20x30cm, Pack of 10	Class IIb	5000223SN000163RH
66800799	RENASYS Soft Port Standalone	One size, Single	Class IIb	5000223SN000173RL

Standards / Common Specification(s) <sup>26</sup> :		
EN ISO 13485: 2016+A11:2021	EN ISO 10993-1: 2020	EN ISO 10993-18:2020/A1:2022
EN ISO 14971: 2019+A11:2021	EN ISO 10993-3: 2014	ISO 10993-23:2021
EN 62366-1: 2015/A1: 2020	EN ISO 10993-5: 2009	EN 13726-1:2002/AC:2003
EN ISO 15223-1: 2021	EN ISO 10993-7: 2008/A1:2022	EN 13726-2: 2002
EN ISO 20417: 2021	EN ISO 10993-10: 2021	EN 13726-3: 2003
EN ISO 780: 2015	EN ISO 10993-11: 2018	EN ISO 11607-1: 2020+A11:2022
EN 556-1: 2001/AC: 2006	EN ISO 10993-17: 2023	EN ISO 11607-2: 2020
EN ISO 14155: 2020	EN ISO 10993-18: 2020/A1:2022	EN ISO 11737-1: 2018/A1:2021
ISTA 2A: 2011	EN ISO 10993-12:2021	EN ISO 11737-2: 2020
EN ISO 14644-1: 2015	EN ISO 10993-17:2023	BS EN ISO 11135-1:2014/A1:2018

Intended Use European Language Translations <sup>27</sup> :			
Language <sup>28</sup>		Code	Intended Use
EN	Local		
Bulgarian	български език	BG	аспирационна помпа (терапия на рани с отрицателно налягане), тъй като тя може да допринесе за зарастването на рани чрез отстраняването на течности, включително иригационни и телесни течности, раневи ексудати и инфекциозни материали. Подходящи типове рани включват: Хронични, Остри, Травматични, Субакутни и дехисцентни рани, Язви (например декубитални или диабетни), Изгаряния с частична дебелина, Клапи, Присадки
Croatian	Hrvatski	HR	Sustav RENASYS indiciran je za pacijente koji bi imali koristi od liječenja rane usisnom pumpom (terapija rane negativnim tlakom) jer može potaknuti cijeljenje rana uklanjanjem tekućina, uključujući tekućine za ispiranje i tjelesne tekućine, eksudata rane i infektivnih materijala. Priladne vrste rana uključuju: Kronične, akutne, traumatske, subakutne i dehiscentne rane, ulkusi (kao što su dekubitalni ili dijabetički), opekline djelomične debljine, reznjeve, graftove (presadke)
Czech	Český Jazyk	CZ	System NPWT RENASYS je indikován pro pacienty, u kterých by bylo přínosné použití odsávacího čerpadla (podtlaková léčba ran), protože jeho použití může urychlit hojení rány prostřednictvím odstraňování tekutin, včetně proplachové tekutiny a tělních tekutin, exsudátu z rány a infekčního materiálu. Příklady typů ran, pro které je tato léčba vhodná: chronické, akutní, traumatické, subakutní rány a rány s dehiscencí, vředy (např. tlakové nebo diabetické), popáleniny druhého stupně, chlopně, kožní štěpy.
Danish	Dansk	DK	RENASYS NPWT-systemet er indiceret til patienter, som vil have gavn af en sugepumpe (sårbehandling med negativt tryk), da den kan fremme sårhelingen ved at fjerne væske, herunder skylle- og kropsvæsker, sårekssudat og infektiøst materiale. Passende sårtyper omfatter: Kroniske, Akutte, Traumatiske, Subakutte og rumperede sår, Sår (i form af tryksår eller diabetessår), Delhudsforbrændinger, Transplantater, Grafts
Dutch	Nederlands	NL	Het RENASYS NDT-systeem is geïndiceerd voor patiënten die baat hebben bij het gebruik van een afzuigpomp (negatieve druktherapie), omdat dit de

			<p>wondgenezing kan bevorderen door verwijdering van vloeistoffen, waaronder irrigatievloeistoffen en lichaamsvloeistoffen, wondexsudaat en infectieus materiaal.</p> <p>In aanmerking komende wondtypen zijn: Chronisch, Acuut, Traumatisch, Subacuut en wonden met dehiscentie, Ulcera (zoals decubituswonden of diabetische ulcera), Tweedegraads brandwonden, Flappen, Transplantaten</p>
Estonian	Eesti	EE	<p>RENASYS-i NPWT süsteem on näidustatud patsientidele, kes võivad saada abi vaakumpumbast (negatiivse rõhuga haavaravist), kuna see võib kiirendada haava paranemist vedelike, sh loputus- ja kehavedelike, eksudaatide ja nakkuslike materjalide eemaldamise kaudu.</p> <p>Kohased haavatüübid on: kroonilised; ägedad; traumaatilised; alaägedad ja dehistsentsiga haavad; haavandid (näiteks lamatishaavandid või diabeetilised haavandid); keskmise sügavusega põletused; lapid; siirikud.</p>
Finnish	Suomi	FI	<p>RENASYS- haavan alipaineimuhoidojärjestelmä on tarkoitettu käytettäväksi potilaille, jotka hyötyvät imupumpun (haavan alipaineimuhoidon) käytöstä, sillä se voi edistää haavan paranemista poistamalla nesteitä, kuten huuhtelu- ja kehon nesteitä, haavan tulehdusnestettä ja infektioita aiheuttavia aineita.</p> <p>Asianmukaisia haavan tyyppejä ovat muun muassa seuraavat: Krooninen, Akuutti, traumaattinen, subakuutit ja auenneet haavat., haavaumat (kuten paine- tai diabeettiset haavat), toisen asteen palovammat, kielekkeet, siirteet</p>
French	Français	FR	<p>d'une pompe d'aspiration (traitement des plaies par pression négative) car elle peut favoriser la cicatrisation de la plaie par retrait des liquides, notamment les liquides d'irrigation et les liquides corporels, exsudats de plaie et matières infectieuses.</p> <p>Les types de plaies indiqués sont les suivants: Chroniques. Aiguës, Traumatiques, Plaies subaiguës et déhiscentes, Ulcères (comme les ulcères de pression ou diabétiques), Brûlures au deuxième degré, Lambeaux, Greffes</p>
German	Deutsch	DE	<p>Das RENASYS NPWT-System ist für Patienten indiziert, die von einer Saugpumpe (Unterdruck-Wundtherapie) profitieren können, da diese die Wundheilung durch das Absaugen von Flüssigkeiten, einschließlich Spülflüssigkeiten und Körperflüssigkeiten, Wundexsudat und infektiösem Material, fördert.</p> <p>Indizierte Wundtypen sind unter anderem:</p>

			Chronische Wunden, Akute Wunden, Traumatische Wunden, Subakute und dehiszente Wunden, Ulzera (z. B. Dekubital- oder diabetische Ulzera), Verbrennungen zweiten Grades, Gewebelappen, Transplantate
Greek	Ελληνικά	GR	Το σύστημα NPWT RENASYS ενδείκνυται για ασθενείς που θα ωφελούνταν από μια αντλία αναρρόφησης (θεραπεία τραύματος με αρνητική πίεση), καθώς μπορεί να συμβάλει στην επούλωση του τραύματος μέσω απομάκρυνσης των υγρών, συμπεριλαμβανομένων των υγρών καταιονισμού και των σωματικών υγρών, των εξιδρωμάτων του τραύματος και των μολυσματικών υλικών. Στους ενδεδειγμένους τύπους τραυμάτων περιλαμβάνονται οι ακόλουθοι: Χρόνια τραύματα, Οξέα τραύματα, Τραύματα κακώσεων, Υποξέα τραύματα και τραύματα που έχουν διαρρηχθεί, Έλκη (όπως τα εκ πίεσης ή τα διαβητικά έλκη), Εγκαύματα μερικού πάχους, Κρημνοί, Μοσχεύματα
Hungarian	Magyar	HU	nyomásos sebkezelés) előnyös lehet, mert elősegíti a seb gyógyulását a folyadékok – köztük az irrigációs folyadékok és a testfolyadékok –, valamint a sebváladékok és a fertőző anyagok eltávolítása révén. A megfelelő sebtípusok közé tartoznak a következők: Krónikus, akut, traumás, szubakut és szétnyílt sebek, fekélyek (pl. nyomásos vagy diabéteszes), részleges mélységű égési sérülések, lebenyek, graftok
Italian	Italiano	IT	Il sistema per terapia NPWT RENASYS è indicato per i pazienti che trarrebbero beneficio da una pompa di aspirazione (terapia a pressione negativa), in quanto può favorire la guarigione della ferita attraverso la rimozione dei liquidi, quali ad esempio fluidi di irrigazione, liquidi corporei, essudati delle ferite e materiali infettivi. Tipi di ferite per le quali la pompa è idonea: ferite croniche, ferite acute, ferite traumatiche, ferite subacute e deiscienti, ulcere (come quelle da pressione o diabetiche), ustioni a spessore parziale, lembi, innesti
Latvian	Latviešu	LV	RENASYS NSBT sistēma ir indicēta pacientiem, kuri gūst labumu no atsūkšanas sūkņa (negatīva spiediena brūču terapija), jo tas var veicināt brūču sadzīšanu, izvadot šķidrumus, tai skaitā skalošanas un ķermeņa šķidrumus, brūču eksudātu un infekciozus materiālus. Atbilstošas brūces ir, piemēram, šādas: hroniskas; akūtas; traumatiskas; subakūtas un atvērušās brūces; čūlas (tādas kā izgulējumi vai diabētiskās); daļēja dziļuma apdegumi; lēveri;

			transplantāti
Lithuanian	Lietuvių	LT	<p>„RENASYS“ NPWT sistema yra indikuojama pacientams, kuriems būtų naudinga naudoti siurbį (neigiamo slėgio žaizdų terapija), nes ji gali paskatinti žaizdų gijimą pašalinant skysčius, įskaitant plovimo ir kūno skysčius, žaizdos eksudatą ir infekcines medžiagas.</p> <p>Tinkami žaizdų tipai: Lėtinės, Ūminės, Trauminės, Apyūmės arba žiojėjančios žaizdos, Opos (pvz., pragulų arba diabetinės), Dalinio storio nudegimai, Lopai, Transplantatai</p>
Polish	Polski	PL	<p>System NPWT RENASYS jest wskazany do stosowania u pacjentów, którzy mogą odnieść korzyść z pompy odsysającej (utrzymywanie podciśnienia nad powierzchnią rany), ponieważ system może sprzyjać gojeniu się ran poprzez usuwanie płynów, w tym płynów irygacyjnych i płynów ustrojowych, wysięków z rany i materiałów zakaźnych.</p> <p>Odpowiednie rodzaje ran to: Rany przewlekłe, Rany ostre, Rany urazowe, Rany podostre i z rozchodzącymi się brzegami, Owrzodzenia (np. odleżynowe lub cukrzycowe), Oparzenia płytkie, Płaty, Przeszczepy</p>
Portuguese	Português	PT	<p>O sistema TFPN RENASYS é indicado para pacientes que possam beneficiar de um equipamento de aspiração (terapia de feridas por pressão negativa), uma vez que pode promover a cicatrização de feridas através da remoção de fluidos, incluindo fluidos de irrigação e corporais, exsudado de feridas e materiais infecciosos.</p> <p>Os tipos de ferida apropriados incluem: Crónica, Aguda, Traumática, Feridas subagudas e deiscuentes, Úlceras (como diabéticas ou por pressão), Queimaduras de espessura parcial, Retalhos, Enxertos</p>
Romanian	Română	RO	<p>Sistemul RENASYS NPWT este indicat pentru pacienții care ar beneficia de pe urma utilizării unei pompe de aspirație (terapie cu presiune negativă a plăgii), deoarece aceasta ar putea susține vindecarea plăgii prin îndepărtarea fluidelor, inclusiv a celor de irigare și a celor corporale, a exsudatului plăgii și a materialelor infecțioase.</p> <p>Tipurile de plăgi potrivite includ: Cronice, Acute, Traumatische, Plăgi subacute și dehiscente, Ulcere (cum ar fi cele de presiune sau diabetice), Arsuri de grosime parțială, Lambouri, Grefe</p>
Slovak	Slovenčina	SK	<p>System RENASYS NPWT je indikovaný u pacientov, ktorí môžu mať úžitok z odsávacej pumpy (liečba</p>

			<p>rany podtlakom), pretože môže podporiť liečbu rany prostredníctvom odsávania tekutín vrátane irigačných a telesných tekutín, exsudátu z rán a infekčných materiálov.</p> <p>Medzi vhodné druhy rán patria: chronické, akútne, úrazové, subakútne a dehiscentné rany, vredy (ako napr. tlakové alebo diabetické), popáleniny čiastočnej hrúbky, neštepené transplantáty, štepy.</p>
Slovenian	Slovenščina	SI	<p>Sistem RENASYS NPWT je indiciran za paciente, ki bi jim sesalna črpalka (zdravljenje ran z negativnim tlakom) koristila, saj lahko pospeši celjenje rane z odstranitvijo tekočin, vključno z izpiralnimi in telesnimi tekočinami, izcedkom iz rane in kužnimi materiali.</p> <p>Med ustreznimi vrstami ran so: kronične; akutne; poškodbene; subakutne in razprte rane; razjede (npr. zaradi pritiska ali diabetične); opekline druge stopnje; prekrvavljeni presadki; presadki.</p>
Spanish	Español	ES	<p>El sistema de TPN RENASYS está indicado para pacientes que pueden beneficiarse de una bomba de aspiración (tratamiento de heridas por presión negativa), puesto que puede favorecer la cicatrización de las heridas mediante la retirada de líquidos, incluidos los líquidos de irrigación y los corporales, el exudado de las heridas y materiales infecciosos.</p> <p>Los tipos de herida adecuados incluyen: Crónica, Aguda, Traumática, Heridas subagudas y dehiscentes, Úlceras (como las úlceras por presión o las diabéticas), Quemaduras de espesor parcial, Colgajos, Injertos</p>
Swedish	Svenska	SE	<p>RENASYS NPWT systemet är indicerat för patienter som skulle gynnas av en sugpump (sårbehandlingssystem med undertryck), då det kan främja sårhäkning genom att avlägsna vätska, inklusive spolningsvätskor och kroppsvätskor, sår-exsudat och infektiösa material.</p> <p>Lämpliga sårtyper inkluderar: Kroniska, Akuta, Traumatiska, subakuta och rupturerade sår, Sår (till exempel på grund av tryck eller diabetes), delhudsbrännskador, lambåer, grafter</p>

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## Appendices - European Language Term Translations:

Appendix no.	Language (EN)	Language (Local)	Country Code
Appendix 1	Bulgarian	български език	BG
Appendix 2	Croatian	Hrvatski	HR
Appendix 3	Czech	Český Jazyk	CZ
Appendix 4	Danish	Dansk	DK
Appendix 5	Dutch	Nederlands	NL
Appendix 6	Estonian	Eesti	EE
Appendix 7	Finnish	Suomi	FI
Appendix 8	French	Français	FR
Appendix 9	German	Deutsch	DE
Appendix 10	Greek	Ελληνικά	GR
Appendix 11	Hungarian	Magyar	HU
Appendix 12	Italian	Italiano	IT
Appendix 13	Latvian	Latviešu	LV
Appendix 14	Lithuanian	Lietuvių	LT
Appendix 15	Polish	Polski	PL
Appendix 16	Portuguese	Português	PT
Appendix 17	Romanian	Română	RO
Appendix 18	Slovak	Slovenčina	SK
Appendix 19	Slovenian	Slovenščina	SI
Appendix 20	Spanish	Español	ES
Appendix 21	Swedish	Svenska	SE

Appendix 1			
Language (EN)	Bulgarian (BG)	Language (Local)	български език
No.	Translated Term		
1	ЕВРОПЕЙСКА ДЕКЛАРАЦИЯ ЗА СЪОТВЕТСТВИЕ		
2	Декларацията потвърждава, че посоченият по-долу продукт съответства на: Регламент 2017/745, [въведете друго уместно европейско законодателство, според приложимото] и се издава единствено на отговорност на име на законния производител		
3	Име на производител		
4	Бизнес адрес		
5	Единен регистрационен номер (EPN)		
6	Упълномощен представител за Европа		
7	Бизнес адрес		
8	Име на продукт: (вижте приложения опис за продуктови кодове/каталожни номера)		
9	Предназначение: Вижте таблицата за други езици		
10	Процедура за оценяване на съответствието (Приложение)		
11	Име на нотифициран орган		
12	Номер на нотифициран орган		
13	Сертификат(и) за проверка		
14	Подписан от името на име на законния производител		
15	Подпис		
16	Име		
17	Длъжност		
18	Дата		
19	Местоположение		
20	Справка за декларация за съответствие		
21	Продуктов опис		
22	Продуктов код / Каталоген номер		
23	Описание на продукта или Вариант на продукта		
24	Класификация в зависимост от риска		
25	Основен уникален идентификатор на изделията - идентификатор на изделията		
26	Стандарти / Обща(и) спецификация(и)		
27	Предназначение: Преводи на европейски езици		
28	Език		

## Appendix 2

Language (EN)	Croatian (HR)	Language (Local)	Hrvatski
<b>No.</b>	<b>Translated Term</b>		
<b>1</b>	EUROPSKA IZJAVA O SUKLADNOSTI		
<b>2</b>	Izjavom se potvrđuje da je niže navedeni proizvod u skladu s: Uredbama 2017/745, [unesite ostale mjerodavne Europske zakone, kako je primjenjivo]. Odgovornost za njeno izdavanje snosi isključivo [naziv proizvođača]		
<b>3</b>	Naziv proizvođača		
<b>4</b>	Adresa proizvođača		
<b>5</b>	Jedinstveni registracijski broj (SRN)		
<b>6</b>	Ovlašteni zastupnik za Europu		
<b>7</b>	Adresa ovlaštenog zastupnika		
<b>8</b>	Naziv proizvoda: (šifre proizvoda/kataloške brojeve potražite u priloženom dodatku)		
<b>9</b>	Namjena: Vidi tablicu za ostale jezike		
<b>10</b>	Postupak procjenjivanja sukladnosti (Prilog)		
<b>11</b>	Naziv prijavljenog tijela		
<b>12</b>	Broj prijavljenog tijela		
<b>13</b>	Potvrda (potvrde) o provjeri		
<b>14</b>	Potpisao/-la u ime [naziv proizvođača]		
<b>15</b>	Potpis		
<b>16</b>	Ime I prezime		
<b>17</b>	Funkcija		
<b>18</b>	Datum		
<b>19</b>	Mjesto		
<b>20</b>	Oznaka izjave o sukladnosti		
<b>21</b>	Dodatak za proizvod		
<b>22</b>	Šifra proizvoda / kataloški broj		
<b>23</b>	Opis proizvoda ili inačica proizvoda		
<b>24</b>	Klasa rizika		
<b>25</b>	Osnovna jedinstvena identifikacija proizvoda-identifikator proizvoda (UDI-DI)		
<b>26</b>	Norme / Uobičajena specifikacija (Uobičajene specifikacije)		
<b>27</b>	Namjena: prijevodi na europske jezike		
<b>28</b>	Jezik		

Appendix 3			
Language (EN)	Czech (CZ)	Language (Local)	Český Jazyk
No.	Translated Term		
1	EVROPSKÉ PROHLÁŠENÍ O SHODĚ		
2	Prohlášení potvrzuje, že níže uvedený výrobek splňuje nařízení 2017/745 [případně doplňte další příslušné evropské právní předpisy], a je vydáno na výhradní zodpovědnost [oficiální název výrobce]		
3	Název výrobce		
4	Adresa místa podnikání		
5	Jediné registrační číslo		
6	Oprávněný zástupce pro Evropu		
7	Adresa místa podnikání		
8	Název výrobku: (kód výrobku / katalogové číslo viz příložený soupis)		
9	Určené použití: Viz tabulka pro další jazyky		
10	Postup posuzování shody (příloha)		
11	Název oznámeného subjektu		
12	Číslo oznámeného subjektu		
13	Osvědčení o ověření		
14	Podepsáno jménem [oficiální název výrobce]		
15	Podpis		
16	Jméno		
17	Pozice		
18	Datum		
19	Místo		
20	Prohlášení o shodě – reference		
21	Soupis výrobků		
22	Kód výrobku / katalogové číslo		
23	Popis výrobku nebo varianta výrobku		
24	Klasifikace rizik		
25	Základní UDI-DI		
26	Normy / společné specifikace		
27	Zamýšlené použití: překlad do evropských jazyků		
28	Jazyk		

Appendix 4			
Language (EN)	Danish (DK)	Language (Local)	Dansk
No.	Translated Term		
1	EUROPÆISK OVERENSSTEMMELSESERKLÆRING		
2	Erklæringen bekræfter, at produkterne angivet herunder overholder: Forordning 2017/745, [indsæt anden gældende europæisk lovgivning hvis relevant] og er udstedt med eneansvar for [Juridisk fabrikantnavn]		
3	Fabrikantens navn		
4	Virksomhedsadresse		
5	Individuelt registreringsnummer (Single Registration Number, SRN)		
6	Autoriseret europæisk repræsentant		
7	Virksomhedsadresse		
8	Produktnavn: (se vedlagte bilag for produktkoder/katalognumre)		
9	Tilslået brug: Se tabel for andre sprog		
10	Procedure for overensstemmelsesvurdering (bilag)		
11	Bemyndiget organ, navn		
12	Bemyndiget organ, nummer		
13	Verifikationscertifikat(er)		
14	Underskrevet på vegne af [Juridisk fabrikantnavn]		
15	Underskrift		
16	Navn		
17	Position		
18	Dato		
19	Placering		
20	Overensstemmelseserklæring, reference		
21	Produktbilag		
22	Produktkode/katalognummer		
23	Produktbeskrivelse eller produktvariant		
24	Risikoklasse		
25	Grundlæggende UDI-DI		
26	Standarder/almindelig(e) specifikation(er)		
27	Tilslået brug: Oversættelser på europæiske sprog		
28	Sprog		

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Appendix 5			
Language (EN)	Dutch (NL)	Language (Local)	Nederlands
No.	Translated Term		
1	EUROPESE CONFORMITEITSVERKLARING		
2	Deze verklaring bevestigt dat het hieronder vermelde product voldoet aan: Verordening 2017/745, [andere relevante Europese wetgeving invoegen indien van toepassing] en wordt uitgegeven onder de uitsluitende verantwoordelijkheid van [wettige naam van fabrikant]		
3	Naam van de fabrikant		
4	Bedrijfsadres		
5	SRN (single registration number: uniek registratienummer)		
6	Geautoriseerde vertegenwoordiger voor Europa		
7	Bedrijfsadres		
8	Productnaam: (zie bijgevoegd bijlage voor productcodes/catalogusnummers)		
9	Beoogd gebruik: Zie de tabel voor andere Europese talen		
10	Conformiteitsbeoordelingsprocedure (bijlage)		
11	Naam van aangemelde instantie		
12	Nummer van aangemelde instantie		
13	Verificatiecertificaat/-certificaten		
14	Ondertekend namens [naam van de fabrikant]		
15	Handtekening		
16	Naam		
17	Functie		
18	Datum		
19	Plaats		
20	Referentie conformiteitsverklaring		
21	Productschema		
22	Productcode/catalogusnummer		
23	Productbeschrijving of productvariant		
24	Risicoclassificatie		
25	Basis UDI-DI		
26	Standaarden/Algemene specificatie(s)		
27	Beoogd gebruik: vertalingen in Europese talen		
28	Taal		

### Appendix 6

Language (EN)	Estonian (EE)	Language (Local)	Eesti
<b>No.</b>	<b>Translated Term</b>		
<b>1</b>	EUROOPA VASTAVUSDEKLARATSIOON		
<b>2</b>	Selle deklaratsiooniga kinnitame allpool loetletud toote vastavust: määrusele 2017/745 [sisestage muu Euroopa õigusakt, kui on kohaldatav] ning see väljastatakse [seadusliku tootja nimi] ainuvastutusel		
<b>3</b>	Tootja nimi		
<b>4</b>	Registreeritud aadress		
<b>5</b>	Unikaalne registreerimisnumber (SRN)		
<b>6</b>	Volitatud esindaja Euroopas		
<b>7</b>	Registreeritud aadress		
<b>8</b>	Toote nimetus: (tootekoode/katalooginumbreid vt lisatud tabelist)		
<b>9</b>	Ettenähtud kasutusotstarve: Teisi keeli vt tabelist		
<b>10</b>	Vastavushindamise protseduur (lisa)		
<b>11</b>	Teavitatud asutuse nimetus		
<b>12</b>	Teavitatud asutuse number		
<b>13</b>	Kinnitussertifikaat/-sertifikaadid		
<b>14</b>	Allkirjastanud [seadusliku tootja nimi]		
<b>15</b>	Allkiri		
<b>16</b>	Nimi		
<b>17</b>	Ametikoht		
<b>18</b>	Kuupäev		
<b>19</b>	Asukoht		
<b>20</b>	Vastavusdeklaratsiooni viide		
<b>21</b>	Toote tabel		
<b>22</b>	Tootekood/katalooginumber		
<b>23</b>	Toote kirjeldus või toote variant		
<b>24</b>	Riski klassifikatsioon		
<b>25</b>	Põhiline UDI-DI		
<b>26</b>	Standardid / ühtsed tehnilised tingimused		
<b>27</b>	Ettenähtud kasutusotstarve Tõlked Euroopa keeltesse		
<b>28</b>	Keel		

### Appendix 7

Language (EN)	Finnish (FI)	Language (Local)	Suomi
<b>No.</b>	<b>Translated Term</b>		
<b>1</b>	EUROOPPALAINEN VAATIMUSTENMUKAISUUSVAKUUTUS		
<b>2</b>	Vakuutuksella vahvistetaan, että jäljempänä mainittu tuote täyttää: Asetuksen 2017/745, [tähän tulee lisätä muu asiaan liittyvä eurooppalainen lainsäädäntö sikäli kuin sitä on] mukaiset vaatimukset, ja annetusta vakuutuksesta vastuussa on yksinomaan [laillisen valmistajan nimi]		
<b>3</b>	Valmistajan nimi		
<b>4</b>	Toimipaikan osoite		
<b>5</b>	Rekisterinumero (SRN)		
<b>6</b>	Eurooppalainen valtuutettu edustaja		
<b>7</b>	Toimipaikan osoite		
<b>8</b>	Tuotteen nimi: (ks. liitteestä tuotekoodit/luettelonumerot)		
<b>9</b>	Käyttötarkoitus: Taulukossa esitetään muut kieliversiot		
<b>10</b>	Vaatimustenmukaisuuden arviointimenettely (Liite)		
<b>11</b>	Ilmoitetun laitoksen nimi		
<b>12</b>	Ilmoitetun laitoksen numero		
<b>13</b>	Tarkastustodistus (-todistukset)		
<b>14</b>	Allekirjoitettu puolesta [laillisen valmistajan nimi]		
<b>15</b>	Allekirjoitus		
<b>16</b>	Nimi		
<b>17</b>	Asema		
<b>18</b>	Päiväys		
<b>19</b>	Paikka		
<b>20</b>	Vaatimustenmukaisuusvakuutuksen viite		
<b>21</b>	Tuoteluettelo		
<b>22</b>	Tuotekoodi / Luettelonumero		
<b>23</b>	Tuotokuvaus tai tuotevariantti		
<b>24</b>	Riskiluokitus		
<b>25</b>	Perus-UDI-DI-tunniste		
<b>26</b>	Standardit / Yhteinen eritelmä (tai monikossa)		
<b>27</b>	Käyttötarkoitus Käännökset Euroopan kielillä		
<b>28</b>	Kieli		

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Appendix 8			
Language (EN)	French (FR)	Language (Local)	Français
No.	Translated Term		
1	DÉCLARATION DE CONFORMITÉ EU		
2	La déclaration confirme que le produit repris ci-dessous est conforme au : Règlement (UE) 2017/745 [insérer au besoin toute autre législation européenne pertinente] et est publiée sous la seule responsabilité de Nom du fabricant légal		
3	Nom du fabricant		
4	Adresse professionnelle		
5	Numéro d'enregistrement unique		
6	Mandataire établi dans l'UE		
7	Adresse professionnelle		
8	Nom du produit : (voir l'annexe jointe pour les codes de produit/références catalogue)		
9	Usage prévu : Voir le tableau pour les autres langues		
10	Procédure d'évaluation de la conformité (Annexe)		
11	Nom de l'organisme notifié		
12	N° de l'organisme notifié		
13	Certificat(s) de vérification		
14	Signé au nom de Nom du fabricant légal		
15	Signature		
16	Nom		
17	Fonction du signataire		
18	Date		
19	Adresse		
20	Référence de la déclaration de conformité		
21	Information produit		
22	Code du produit / Référence catalogue du produit		
23	Description du produit ou variante du produit		
24	Classe de risque		
25	Identifiant « dispositif » IUD (IUD-ID)		
26	Normes / Spécification(s) commune(s)		
27	Usage prévu : traduction dans les langues européennes		
28	Langue		

Appendix 9			
Language (EN)	German (DE)	Language (Local)	Deutsch
No.	Translated Term		
1	EUROPÄISCHE KONFORMITÄTSERKLÄRUNG		
2	Mit dieser Erklärung wird bestätigt, dass das unten aufgeführte Produkt den folgenden Anforderungen entspricht: Verordnungen 2017/745, [ggf. andere einschlägige europäische Rechtsvorschriften einfügen]. Die alleinige Verantwortung für die Ausstellung dieser Konformitätserklärung trägt [Name des Herstellers]		
3	Name des Herstellers		
4	Geschäftsadresse		
5	Einmalige Registrierungsnummer (SRN)		
6	Europäischer Bevollmächtigter		
7	Geschäftsadresse		
8	Produktname: (Produktcodes/Katalognummern siehe beigefügtes Verzeichnis)		
9	Verwendungszweck: Andere Sprachen siehe Tabelle		
10	Konformitätsbewertungsverfahren (Anhang)		
11	Name der benannten Stelle		
12	Nummer der benannten Stelle		
13	Prüfzertifikat(e)		
14	Unterzeichnet im Auftrag von Name des Herstellers		
15	Unterschrift		
16	Name		
17	Position		
18	Datum		
19	Standort		
20	Konformitätserklärung – Referenz		
21	Produktverzeichnis		
22	Produktcode/Katalognummer		
23	Produktbeschreibung oder Produktvariante		
24	Risikoklassifizierung		
25	Basis-UDI-DI		
26	Normen/Gemeinsame Spezifikation(en)		
27	Verwendungszweck: Übersetzung in europäische Sprachen		
28	Sprache		

### Appendix 10

Language (EN)	Greek (GR)	Language (Local)	Ελληνικά
No.	Translated Term		
1	ΕΥΡΩΠΑΪΚΗ ΔΗΛΩΣΗ ΣΥΜΜΟΡΦΩΣΗΣ		
2	Η δήλωση επιβεβαιώνει ότι το προϊόν που αναφέρεται παρακάτω πληροί: τους κανονισμούς 2017/745, [συμπληρώστε άλλη σχετική ευρωπαϊκή νομοθεσία ανάλογα με την περίπτωση] και εκδίδεται υπό την αποκλειστική ευθύνη του [επωνυμία νόμιμου κατασκευαστή]		
3	Επωνυμία κατασκευαστή		
4	Διεύθυνση επιχείρησης		
5	Ενιαίος αριθμός καταχώρισης (SRN)		
6	Εξουσιοδοτημένος αντιπρόσωπος στην Ευρώπη		
7	Διεύθυνση επιχείρησης		
8	Όνομασία προϊόντος: (βλ. συνημμένο παράρτημα κωδικών προϊόντων/αριθμών καταλόγου)		
9	Προβλεπόμενη χρήση: βλ. πίνακα για άλλες γλώσσες		
10	Διαδικασία εκτίμησης της συμμόρφωσης (παράρτημα)		
11	Επωνυμία κοινοποιημένου οργανισμού		
12	Αριθμός κοινοποιημένου οργανισμού		
13	Πιστοποιητικό(ά) επαλήθευσης		
14	Υπογραφή εξ ονόματος του [επωνυμία νόμιμου κατασκευαστή]		
15	Υπογραφή		
16	Όνοματεπώνυμο		
17	Τίτλος		
18	Ημερομηνία		
19	Τοποθεσία		
20	Αναφορά δήλωσης συμμόρφωσης		
21	Παράρτημα προϊόντων		
22	Κωδικός προϊόντος/Αριθμός καταλόγου		
23	Περιγραφή προϊόντος ή παραλλαγή προϊόντος		
24	Ταξινόμηση κινδύνου		
25	Βασικό UDI-DI		
26	Πρότυπα/Κοινή(ές) προδιαγραφή(ές)		
27	Προβλεπόμενη χρήση: μεταφράσεις σε ευρωπαϊκές γλώσσες		
28	Γλώσσα		

### Appendix 11

Language (EN)	Hungarian (HU)	Language (Local)	Magyar
<b>No.</b>	<b>Translated Term</b>		
1	EURÓPAI MEGFELELŐSÉGI NYILATKOZAT		
2	A nyilatkozat megerősíti, hogy az alább felsorolt termék megfelel a következőknek: A 2017/745 rendeletek, [értelemszerűen illessze be ide az egyéb fontos európai jogszabályokat], és kiadása a [gyártó hivatalos neve] kizárólagos felelősségére történik		
3	A gyártó neve		
4	Székhelye		
5	Egyedi nyilvántartási szám (SRN)		
6	Meghatalmazott európai képviselő		
7	Székhelye		
8	A termék neve: (lásd a mellékelt listát a termékkódokat/katalógusszámokat illetően)		
9	Rendeltetésszerű használat: Az egyéb nyelveket lásd a táblázatban		
10	Megfelelőségértékelési eljárás (melléklet)		
11	Kijelölt szervezet neve		
12	Kijelölt szervezet száma		
13	Hitelesítési tanúsítvány(ok)		
14	Aláírva a [gyártó hivatalos neve] nevében		
15	Aláírás		
16	Név		
17	Beosztás		
18	Dátum		
19	Hely		
20	A megfelelőségi nyilatkozat hivatkozása		
21	Terméklista		
22	Termékkód/katalógusszám		
23	A termék leírása vagy termékváltozat		
24	Kockázatbesorolás		
25	Alap UDI-DI		
26	Szabványok / általános specifikáció(k)		
27	A rendeltetésszerű használat európai nyelvre történt fordítása		
28	Nyelv		

## Appendix 12

Language (EN)	Italian (IT)	Language (Local)	Italiano
No.	Translated Term		
1	DICHIARAZIONE DI CONFORMITÀ EUROPEA		
2	La dichiarazione conferma che il prodotto menzionato di seguito è conforme a: Regolamento 2017/745, [inserire altre normative europee pertinenti per quanto applicabile], ed è rilasciata sotto l'esclusiva responsabilità del fabbricante legale		
3	Nome del fabbricante		
4	Indirizzo aziendale		
5	Numero di registrazione unico (Single Registration Number, SRN)		
6	Rappresentante europeo autorizzato		
7	Indirizzo aziendale		
8	Nome del prodotto: (vedere il prospetto allegato per i codici di prodotto/numeri di catalogo)		
9	Uso previsto: vedere la tabella per le altre lingue		
10	Procedura di valutazione di conformità (Allegato)		
11	Nome dell'organismo notificato		
12	Numero dell'organismo notificato		
13	Certificazione/i di verifica		
14	Firmato in nome e per conto di (nome del fabbricante legale)		
15	Firma		
16	Nome		
17	Posizione professionale		
18	Data		
19	Sede		
20	Riferimento per la Dichiarazione di conformità		
21	Prospetto prodotti		
22	Codice prodotto/Numero di catalogo		
23	Descrizione del prodotto o variante di prodotto		
24	Classificazione del rischio		
25	Codice UDI-DI		
26	Norme/Specifiche comuni		
27	Uso previsto: traduzioni nelle lingue europee		
28	Lingua		

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Appendix 13			
Language (EN)	Latvian (LV)	Language (Local)	Latviešu
No.	Translated Term		
1	EIROPAS ATBILSTĪBAS DEKLARĀCIJA		
2	Deklarācija apliecina, ka tālāk norādītais produkts atbilst: Regulām 2017/745, [ievietojiet citus atbilstošus Eiropas tiesību aktus, kā nepieciešams], un tā ir izsniegta tikai uz [ražotāja juridiskais nosaukums] atbildību		
3	Ražotāja nosaukums		
4	Uzņēmuma adrese		
5	Vienotais reģistrācijas numurs (VRN)		
6	Pilnvarotais pārstāvis Eiropā		
7	Uzņēmuma adrese		
8	Produkta nosaukums: (produkta kodus/kataloga numurus skatīt pievienotajā pielikumā)		
9	Paredzētā lietošana: informāciju par citām valodām skatīt tabulā		
10	Atbilstības novērtēšanas procedūra (Pielikums)		
11	Paziņotās struktūras nosaukums		
12	Paziņotās struktūras numurs		
13	Pārbaudes sertifikāts(-i)		
14	Parakstīts [ražotāja juridiskais nosaukums] vārdā		
15	Paraksts		
16	Vārds, uzvārds		
17	Amats		
18	Datums		
19	Vieta		
20	Atbilstības deklarācijas atsauce		
21	Produkta pielikums		
22	Produkta kods/kataloga numurs		
23	Produkta apraksts vai produkta variants		
24	Riska klasifikācija		
25	Pamata UDI-DI		
26	Standarti/vispārīgā(-s) specifikācija(-s)		
27	Paredzētā lietošana: tulkojumi Eiropas valodās		
28	Valoda		

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### Appendix 14

Language (EN)	Lithuanian (LT)	Language (Local)	Lietuvių
No.	Translated Term		
1	Europos Atitikties Deklaracija		
2	Delaracija patvirtina kad toliau išvardyti produktai atitinka: Reglamentą 2017/745, [įterpti kitus taikytinus Europos teisės aktus] ir už jo išdavimą yra visiškai atsakingas [legalus gamintojo vardas].		
3	Gamintojo pavadinimas		
4	Verslo adresas		
5	Bendras Registracijos Numeris (BRN)		
6	Europos įgaliotasis atstovas		
7	Verslo adresas		
8	Produkto vardas: (produktų kodus / katalogo numerius žiūrėkite priede)		
9	Paskirtis: kitomis kalbomis žiūrėkite lentelę		
10	Atitikties deklaracija (priedas)		
11	Notifikuotosios įstaigos pavadinimas		
12	Notifikuotosios įstaigos numeris		
13	Patvirtinimo sertifikatas (-ai)		
14	Pasirašyta (legalaus gamintojo vardas) vardu		
15	Parašas		
16	Vardas		
17	Pareigos		
18	Data		
19	Vieta		
20	Atitikties Deklaracijos Nuoroda		
21	Produktų sąrašas		
22	Produkto Kodas/ Katalogo numeris		
23	Produkto Apibūdinimas arba Produkto Variantas		
24	Rizikos Klasifikacija		
25	Pagrindinis UDI		
26	Standartai / Bendroji specifikacija (-os)		
27	Numatomi vartoti Europos šalių kalbų vertimai		
28	Kalba		

Appendix 15			
Language (EN)	Polish (PL)	Language (Local)	Polski
No.	Translated Term		
1	EUROPEJSKA DEKLARACJA ZGODNOŚCI		
2	Deklaracja potwierdza, że wymieniony poniżej produkt spełnia wymagania: Rozporządzenia 2017/745 [w razie potrzeby wstawić inne stosowne przepisy europejskie] i jest wydawana na wyłączną odpowiedzialność Nazwa producenta		
3	Nazwa producenta		
4	Adres firmy		
5	Niepowtarzalny numer rejestracyjny (SRN)		
6	Upoważniony przedstawiciel w Unii Europejskiej		
7	Adres firmy		
8	Nazwa produktu: (kody produktów / numery katalogowe zawiera załączony wykaz)		
9	Przewidziane używanie : Tekst w innych językach znajduje się w tabeli		
10	Procedura oceny zgodności (załącznik)		
11	Nazwa jednostki notyfikowanej		
12	Numer jednostki notyfikowanej		
13	Certyfikaty weryfikacji		
14	Podpisano w imieniu Nazwa producenta		
15	Podpis		
16	Imię i nazwisko		
17	Stanowisko		
18	Data		
19	Miejsce		
20	Numer referencyjny deklaracji zgodności		
21	Wykaz produktów		
22	Kod produktu / numer katalogowy		
23	Opis produktu lub wariant produktu		
24	Klasyfikacja ryzyka		
25	Kod Basic UDI-DI		
26	Normy / wspólne specyfikacje		
27	Tłumaczenia tekstu dotyczącego przeznaczenia produktu na języki europejskie		
28	Język		

Appendix 16			
Language (EN)	Portuguese (PT)	Language (Local)	Português
No.	Translated Term		
1	DECLARAÇÃO DE CONFORMIDADE EUROPEIA		
2	A declaração confirma que os produtos listados abaixo cumprem: Regulamentação 2017/745, [inserir outra legislação europeia relevante, conforme aplicável] e é emitida sob a responsabilidade única do [Nome legal do fabricante]		
3	Nome do fabricante		
4	Endereço da empresa		
5	Número único de registo (NUR)		
6	Representante Europeu Autorizado		
7	Endereço da empresa		
8	Nome do produto: (consulte o anexo quanto a códigos de produtos/números de catálogo)		
9	Finalidade: Consulte a tabela para outros idiomas		
10	Procedimento de avaliação de conformidade (Anexo)		
11	Nome do organismo notificado		
12	Número do organismo notificado		
13	Certificado(s) de verificação		
14	Assinado em nome de [Nome legal do fabricante]		
15	Assinatura		
16	Nome		
17	Cargo		
18	Data		
19	Localização		
20	Referência de Declaração de conformidade		
21	Anexo do produto		
22	Código de produto / Número de catálogo		
23	Descrição do produto ou variante do produto		
24	Classificação de risco		
25	UDI-DI básico		
26	Normas / Especificação(ões) comum(ns)		
27	Traduções da Finalidade para idiomas europeus		
28	Idioma		

Appendix 17			
Language (EN)	Romanian (RO)	Language (Local)	Română
No.	Translated Term		
1	DECLARAȚIE DE CONFORMITATE EUROPEANĂ		
2	Declarația confirmă faptul că produsul specificat mai jos respectă: Regulamentul 2017/745, [introduceți ale acte legislative europene relevante, după caz] și este emis pe propria răspundere a Denumirea juridică a producătorului		
3	Denumirea producătorului		
4	Sediul social		
5	Număr unic de înregistrare (CUI)		
6	Reprezentant european autorizat		
7	Sediul social		
8	Denumirea produsului: (consultați anexa atașată pentru codurile de produs/numerele de catalog)		
9	Utilizare preconizată: consultați tabelul pentru alte limbi		
10	Procedura de evaluare a conformității (Anexă)		
11	Denumirea organismului notificat		
12	Numărul organismului notificat		
13	Certificat(e) de verificare		
14	Semnat în numele Denumirea juridică a producătorului		
15	Semnătură		
16	Nume		
17	Funcție		
18	Dată		
19	Locație		
20	Referință pentru declarația de conformitate		
21	Anexa produsului		
22	Cod produs / Număr de catalog		
23	Descrierea produsului sau varianta produsului		
24	Clasificarea riscurilor		
25	UDI-DI (identificator unic de dispozitiv) de bază		
26	Standarde / Specificație(i) comună(e)		
27	Utilizare preconizată: traduceri în limbile europene		
28	Limbă		

Appendix 18			
Language (EN)	Slovak (SK)	Language (Local)	Slovenčina
No.	Translated Term		
1	VYHLÁSENIE O ZHODE EÚ		
2	Vyhlásenie potvrdzuje, že nižšie uvedený produkt spĺňa: nariadenia 2017/745, [vložiť ďalšie príslušné právne predpisy EÚ] a vydáva sa s výhradnou zodpovednosťou výrobcu s registrovaným názvom		
3	Názov výrobcu		
4	Sídlo spoločnosti		
5	Jediné registračné číslo (SRN)		
6	Oprávnený zástupca pre EÚ		
7	Sídlo spoločnosti		
8	Názov produktu: (pozri priložený dodatok s kódmi výrobkov/katalógovými číslami)		
9	Plánované použitie: Ďalšie jazyky nájdete v tabuľke		
10	Postup posudzovania zhody (príloha)		
11	Názov notifikovaného orgánu		
12	Číslo notifikovaného orgánu		
13	Overovacie certifikáty		
14	Podpísaný v mene výrobcu s registrovaným názvom		
15	Podpis		
16	Meno		
17	Pozícia		
18	Dátum		
19	Miesto		
20	Odkaz na vyhlásenie o zhode		
21	Tabuľka výrobkov		
22	Kód výrobku / katalógové číslo		
23	Popis produktu alebo variant produktu		
24	Klasifikácia rizika		
25	Základný identifikátor UDI-DI		
26	Normy / spoločné špecifikácie		
27	Plánované použitie prekladov z jazykov EÚ		
28	Jazyk		

### Appendix 19

Language (EN)	Slovenian (SI)	Language (Local)	Slovenščina
No.	Translated Term		
1	EVROPSKA IZJAVA O SKLADNOSTI		
2	Izjava potrjuje, da spodaj navedeni izdelek ustreza: Uredbi 2017/745 [vstavite drugo zadevno evropsko zakonodajo, kakor je primerno], in je izdana na lastno odgovornost [Ime zakonitega proizvajalca]		
3	Ime proizvajalca		
4	Poslovni naslov		
5	Enotna registrska številka (SRN)		
6	Pooblaščen zastopnik za Evropo		
7	Poslovni naslov		
8	Ime izdelka: (glejte priložen dodatek s kodami/kataloškiimi številkami izdelkov)		
9	Predvidena uporaba: Za druge jezike glejte preglednico		
10	Postopek ugotavljanja skladnosti (Priloga)		
11	Ime priglašene organa		
12	Številka priglašene organa		
13	Potrdilo(-a) o verifikaciji		
14	Podpisano v imenu Ime zakonitega proizvajalca		
15	Podpis		
16	Ime		
17	Delovno mesto		
18	Datum		
19	Kraj		
20	Referenca Izjave o skladnosti		
21	Dodatek z izdelki		
22	Koda/kataloška številka izdelka		
23	Opis izdelka ali različica izdelka		
24	Razvrščanje v razred tveganja		
25	Osnovni UDI-DI		
26	Standardi/splošne specifikacije		
27	Prevodi predvidene uporabe v evropske jezike		
28	Jezik		

Appendix 20			
Language (EN)	Spanish (ES)	Language (Local)	Español
No.	Translated Term		
1	DECLARACIÓN UE DE CONFORMIDAD		
2	Esta declaración confirma que el producto indicado a continuación cumple con lo estipulado en el Reglamento (UE) 2017/745, [incluir otras normativas europeas pertinentes que sean de aplicación] y se publica bajo la exclusiva responsabilidad de [Nombre legal del fabricante]		
3	Nombre del fabricante		
4	Domicilio social		
5	Número de registro único (SRN)		
6	Representante autorizado en Europa		
7	Domicilio social		
8	Nombre del producto: (véase el apéndice para comprobar los códigos/números de catálogo de los productos)		
9	Uso previsto: véase la tabla para consultar otros idiomas		
10	Procedimiento de evaluación de la conformidad (anexo)		
11	Nombre del organismo notificado		
12	Número del organismo notificado		
13	Certificados de verificación		
14	Firmado en nombre de [Nombre legal del fabricante]		
15	Firma		
16	Nombre		
17	Puesto		
18	Fecha		
19	Ubicación		
20	Referencia de la declaración de conformidad		
21	Apéndice del producto		
22	Código/número de catálogo del producto		
23	Descripción o variante del producto		
24	Clasificación del riesgo		
25	UDI-DI básica		
26	Normas/especificaciones comunes		
27	Uso previsto: traducciones a idiomas europeos		
28	Idioma		

Appendix 21			
Language (EN)	Swedish (SE)	Language (Local)	Svenska
No.	Translated Term		
1	EUROPEISK FÖRSÄKRAN OM ÖVERENSSTÄMMELSE		
2	Denna försäkran bekräftar att produkten som anges nedan uppfyller: kraven i förordning 2017/745, [infoga annan relevant Europeisk lagstiftning om tillämpligt] och utfärdas på eget ansvar av [tillverkarens namn]		
3	Tillverkarens namn		
4	Företagsadress		
5	Eudamed-registreringsnummer (SRN)		
6	Auktoriserad representant i Europa		
7	Företagsadress		
8	Produktnamn: (se den bifogade översikten för produktkoder/katalognummer)		
9	Avsedd användning: Se tabellen för andra språk		
10	Procedur för bedömning av överensstämmelse (bilaga)		
11	Anmälda organets namn		
12	Anmälda organets identifikationsnummer		
13	Verifieringscertifikat		
14	Undertecknat på [tillverkarens namn]:s vägnar		
15	Underskrift		
16	Namn		
17	Befattning		
18	Datum		
19	Placering		
20	Referens för försäkran om överensstämmelse		
21	Produktöversikt		
22	Produktkod/katalognummer		
23	Produktbeskrivning eller produktvariant		
24	Riskklassificering		
25	Grundläggande UDI-DI		
26	Standarder/gemensam(ma) specifikation(er)		
27	Avsedd användning av översättningar till europeiska språk		
28	Språk		



By Royal Charter

# EU Quality Assurance Certificate

Regulation (EU) 2017/745, Annex XI Part A

## MDR 737173 R000

**Manufacturer:** Smith & Nephew Medical Ltd

**Address:**

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United Kingdom

**Single Registration Number:** Not Available

**EU Authorised Representative:** Smith & Nephew Operations B.V.

**Address:**

Bloemlaan 2  
2132 NP  
Hoofddorp  
The Netherlands

**Scope:** See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex XI part A, the quality system meets the requirements of the Regulation. For the placing on the market of Class III and Class IIb devices an additional Annex X certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2021-06-07**

Date: **2021-06-07**

Expiry Date: **2026-06-06**

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Page 1 of 3

Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.  
This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80  
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By Royal Charter

# EU Quality Assurance Certificate

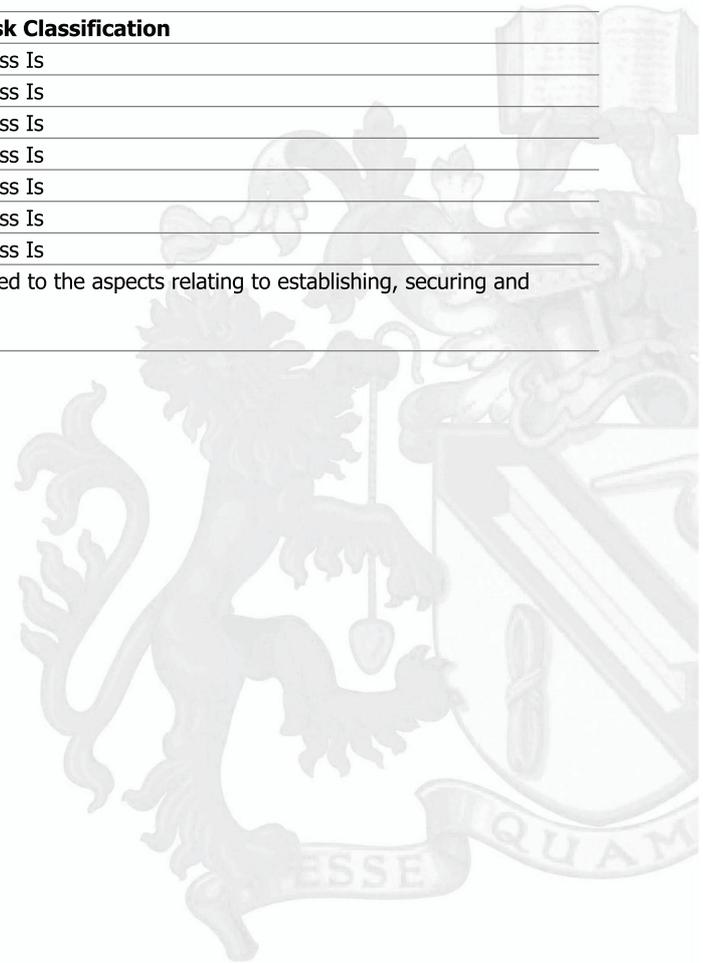
Regulation (EU) 2017/745, Annex XI Part A

## MDR 737173 R000

### Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Low adherent absorbent dressings	Class Is
Non-woven dressings	Class Is
Catheter dressings	Class Is
Catheter fixation dressings	Class Is
Non-woven adhesive dressings	Class Is
Skin stapler handle	Class Is
Absorbent tracheostomy dressings	Class Is

For Class Is devices, the Notified Body conformity assessment is limited to the aspects relating to establishing, securing and maintaining sterile conditions.



First Issued: **2021-06-07**

Date: **2021-06-07**

Expiry Date: **2026-06-06**

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Page 2 of 3

Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.  
This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80  
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.  
A Member of the BSI Group of Companies.



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# EU Quality Assurance Certificate

Regulation (EU) 2017/745, Annex XI Part A

## MDR 737173 R000

### Certificate History

*(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)*

Date	Reference number	Action
Current	3258304	Issued



First Issued: **2021-06-07**

Date: **2021-06-07**

Expiry Date: **2026-06-06**

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Page 3 of 3

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A Member of the BSI Group of Companies.

Smith & Nephew Medical Ltd.  
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Hull, HU3 2BN  
England

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www.smith-nephew.com

# Smith+Nephew

## EUROPEAN DECLARATION OF CONFORMITY

This Declaration confirms that the product listed below meets the Essential Requirements set out in Annex I of the Council Directive 93/42/EEC (as amended).

<b>Manufacturer's Name :</b>	Smith & Nephew Medical Limited
<b>Business Address:</b>	101 Hessle Road, Hull, HU3 2BN, United Kingdom.
<b>Authorised Representative :</b>	Smith & Nephew Orthopaedics GmbH, Alemannenstraße 14, 78532 Tuttlingen, Germany
<b>Medical Devices:</b>	RENASYS-F Foam Dressing kit with Soft Port RENASYS Soft Port Foam Wound Dressing for use with PICO and RENASYS NPWT Systems
<b>Classification:</b>	Class IIb
<b>GMDN Code and Term:</b>	34059 – Wound dressing kit, medicated, sterile
<b>Scope of Application:</b>	All batches supplied to which the Declaration of Conformity Procedure has been applied.
<b>Declaration:</b>	Conformity of the product has been assessed in accordance with Annex II of the Directive. A dossier of technical documentation, as required by the Directive is available. The product listed is designed, manufactured and tested in accordance with the information set out in the dossier.
<b>Verification Certificate(s):</b>	EC Certificate No. CE 00356 Full Quality Assurance. Notified Body No. 2797 (British Standards Institution) British Standards Institution. Certificate No. MD 76718 Quality Management System (BS EN ISO 13485) British Standards Institution. Certificate No. FM 24676 Quality Management System (BS EN ISO 9001)
<b>Standards Applied:</b>	BS EN ISO 9001:2015 BS EN ISO 13485: 2016/A11:2021 EN ISO 10993-1:2020 BS EN ISO 10993-3:2014 BS EN ISO 10993-5:2009 BS EN ISO 10993-7:2008/AC:2009 BS EN ISO 10993-10:2023 BS EN ISO 10993-11:2018 BS EN ISO 10993-12:2021 BS EN ISO 10993-17: 2009 BS EN ISO 10993-18:2020 BS EN ISO 10993-23:2021 BS EN 556-1:2001/AC:2006 BS EN ISO 20417:2021 BS EN ISO 780:2015 BS EN ISO 15223-1:2016 BS EN ISO 11135:2014/A1:2019 BS EN ISO 11607-1:2020 ISO 11607-2:2019 BS EN ISO 11737-1:2018+/A1:2021 BS EN ISO 11737-2:2020

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	BS EN ISO 14644-1:2015 BS EN ISO 14971: 2019/A11:2021 ISTA 2A	
<b>Product Codes:</b>	<b>Code</b>	<b>Size</b>
	66800794	Small Kit A kit contains: a) 1 Soft Port dressing, b) 1 foam dressing 10cm x 8cm x 3cm/3.9in x 3.1in x 1.2in, c) 1 Drape 8in x 12in or 20cm x 30cm
	66800795	Medium Kit A kit contains: a) 1 Soft Port dressing, b) 1 foam dressing 20cm x 12.5 cm x 3cm/ 7.9in x 4.9in x 1.2in, c) 2 Drape 8in x 12in or 20cm x 30cm
	66800799	N/A – one size
	66800796	Large Kit A kit contains: a) 1 Soft Port dressing, b) 1 foam dressing 25cm x 15cm x 3cm, c) 3 Drape 8in x 12in or 20cm x 30cm
	66800797	X-Large Kit A kit contains: a) 1 Soft Port dressing, b) 1 foam dressing 50cm x 63cm x 1.5cm, c) 6 Drape 8in x 12in or 20cm x 30cm
	66801021	10cm x 12.5cm
	66801668	Small Kit. Kit component sealed inside a pouch. 5 pouches inside a bag
	66801669	Medium Kit. Kits component sealed inside a pouch. 5 pouches inside a bag.
	66801670	Large Kit. Kits component sealed inside a pouch. 5 pouches inside a bag
	66801671	X-Large Kit. Kits component sealed inside a pouch. 5 pouches inside a bag
	66801673	Soft Port kits component sealed inside a pouch. 5 pouches inside a bag

**Authorised Signatory:****Name:**

Andrew Daghish

**Position:**

Regulatory Affairs Manager

**Signed:**

DocuSigned by:  
  
Signer Name: Andrew Daghish  
Signing Reason: I approve this document  
Signing Time: 10-Apr-2024 | 19:11:00 BST  
303C90DE917A4F32AA0ABF5C275816BC

**Dated:**

10-Apr-2024 | 19:11:17 BST

**Certificate Reference:**

HU/135 issue 017

**Smith & Nephew Medical Limited**

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England

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**Manufacturer's Confirmation in regard to Regulation 2023/607**

*with respect to the certificates issued under Council Directive 93/42/EEC on medical devices ("MDD"), ("Directive Certificates") and their validity per Article 120(2) of Regulation (EU) 2017/745 on medical devices as amended by Regulation 2023/607 of 20 March 2023 ("MDR") and with respect to the Devices' and its Manufacturer's compliance with the conditions to continued placing on the market as per Article 120(3) of the MDR*

Manufacturer name	Smith & Nephew Medical Ltd.
Manufacturer address	101 Hessle Road Hull HU3 2BN United Kingdom
Manufacturer EUDAMED SRN	GB-MF-000017580
Notified Body name	BSI
Notified Body number	2797

This is confirmation that the devices listed below meet following conditions for extension of certificates issued under Council Directive Council Directive 93/42/EEC on medical devices (MDD) as stated in Regulation (EU) 2023/607 amending Regulation (EU) 2017/745 on medical devices

- The certificate(s) covering the listed devices was valid on the 26 May 2021.
- The device(s) continue to comply with Directive 93/42/EEC (MDD)
- There are no significant changes in the design and intended purpose since 26 May 2021.
- The device(s) do not present unacceptable risks to health or safety of patients, users or other persons, or to other aspects of the protection of public health
- A quality management system in accordance with Article 10(9), Regulation (EU) 2017/745 (MDR) has been put in place by the manufacturer no later than 26 May 2024.
- A formal application to the notified body in accordance with Section 4.3, first subparagraph, of Annex VII, Regulation (EU) 2017/745 (MDR) for conformity assessment has been made for the device(s) listed and a signed written agreement is in place in accordance with Section 4.3, second subparagraph, of Annex VII, Regulation (EU) 2017/745 (MDR). This was completed prior to the expiry of the certificate
- Post-market surveillance, market surveillance, vigilance, registration of economic operators in accordance with Regulation (EU) 2017/745 (MDR) is in place for the device(s) listed.

Signature:

DocuSigned by:  
  
 Signer Name: Andrew Daghli  
Signing Reason: I approve this document  
Signing Time: 15-May-2024 | 10:05:38 BST  
303C90DE917A4F32AA0ABF5C275816BC

Date: 15-May-2024 | 10:05:42 BST

Print name: Andrew Daghli

Title/position: Regulatory Affairs Manager

**Schedule of devices**

Catalog Item	Description	Certificate number	Expiry date on the certificate	Extended expiry date
66802000	PICO 7 Multisite Small 15cm x 20cm	CE 00356	26 <sup>th</sup> May 2024	31st Dec 2028
66802001	PICO 7 MULTISITE LARGE 20CM X 25CM	CE 00356	26 <sup>th</sup> May 2024	31st Dec 2028
66802002	PICO 7 10cm x 20cm	CE 00356	26 <sup>th</sup> May 2024	31st Dec 2028
66802003	PICO 7 10cm x 30cm	CE 00356	26 <sup>th</sup> May 2024	31st Dec 2028
66802004	PICO 7 10cm x 40cm	CE 00356	26 <sup>th</sup> May 2024	31st Dec 2028
66802005	PICO 7 15cm x 15cm	CE 00356	26 <sup>th</sup> May 2024	31st Dec 2028
66802006	PICO 7 15cm x 20cm	CE 00356	26 <sup>th</sup> May 2024	31st Dec 2028
66802007	PICO 7 15cm x 30cm	CE 00356	26 <sup>th</sup> May 2024	31st Dec 2028
66802008	PICO 7 20cm x 20cm	CE 00356	26 <sup>th</sup> May 2024	31st Dec 2028
66802009	PICO 7 25cm x 25cm	CE 00356	26 <sup>th</sup> May 2024	31st Dec 2028
66802010	PICO 7 Single Drsg M/Site Small 15x20cm	CE 00356	26 <sup>th</sup> May 2024	31st Dec 2028
66802011	PICO 7 Single Drsg M/Site Large 20x25cm	CE 00356	26 <sup>th</sup> May 2024	31st Dec 2028
66802012	PICO 7 Single Dressing 10cm x 20cm	CE 00356	26 <sup>th</sup> May 2024	31st Dec 2028
66802013	PICO 7 Single Dressing 10cm x 30cm	CE 00356	26 <sup>th</sup> May 2024	31st Dec 2028
66802014	PICO 7 Single Dressing 10cm x 40cm	CE 00356	26 <sup>th</sup> May 2024	31st Dec 2028
66802015	PICO 7 Single Dressing 15cm x 15cm	CE 00356	26 <sup>th</sup> May 2024	31st Dec 2028
66802016	PICO 7 Single Dressing 15cm x 20cm	CE 00356	26 <sup>th</sup> May 2024	31st Dec 2028
66802017	PICO 7 Single Dressing 15cm x 30cm	CE 00356	26 <sup>th</sup> May 2024	31st Dec 2028
66802018	PICO 7 Single Dressing 20cm x 20cm	CE 00356	26 <sup>th</sup> May 2024	31st Dec 2028
66802019	PICO 7 Single Dressing 25cm x 25cm	CE 00356	26 <sup>th</sup> May 2024	31st Dec 2028
66802020	PICO MULTISITE SMALL DRESSING - 5 PACK	CE 00356	26 <sup>th</sup> May 2024	31st Dec 2028
66802021	PICO MULTISITE LARGE DRESSING - 5 PACK	CE 00356	26 <sup>th</sup> May 2024	31st Dec 2028
66802022	PICO 10cm x 20cm DRESSING - 5 PACK	CE 00356	26 <sup>th</sup> May 2024	31st Dec 2028
66802023	PICO 10cm x 30cm DRESSING - 5 PACK	CE 00356	26 <sup>th</sup> May 2024	31st Dec 2028
66802024	PICO 10cm x 40cm Dressing - 5 Pack	CE 00356	26 <sup>th</sup> May 2024	31st Dec 2028
66802025	PICO 15cm x 15cm Dressing - 5 Pack	CE 00356	26 <sup>th</sup> May 2024	31st Dec 2028
66802026	PICO 15cm x 20cm Dressing - 5 Pack	CE 00356	26 <sup>th</sup> May 2024	31st Dec 2028
66802027	PICO 15cm x 30cm Dressing - 5 Pack	CE 00356	26 <sup>th</sup> May 2024	31st Dec 2028
66802028	PICO 20cm x 20cm Dressing - 5 Pack	CE 00356	26 <sup>th</sup> May 2024	31st Dec 2028

Catalog Item	Description	Certificate number	Expiry date on the certificate	Extended expiry date
66802029	PICO 25cm x 25cm Dressing - 5 Pack	CE 00356	26 <sup>th</sup> May 2024	31st Dec 2028
66802031	PICO 7Y SINGLE USE NPWT SYSTEM	CE 00356	26 <sup>th</sup> May 2024	31st Dec 2028
66802040	PICO 14 MULTISITE SMALL 15x20cm CTN1	CE 00356	26 <sup>th</sup> May 2024	31st Dec 2028
66802041	PICO 14 MULTISITE LARGE 20x25cm CTN1	CE 00356	26 <sup>th</sup> May 2024	31st Dec 2028
66802042	PICO 14 10x20cm CTN1	CE 00356	26 <sup>th</sup> May 2024	31st Dec 2028
66802043	PICO 14 10x30cm CTN1	CE 00356	26 <sup>th</sup> May 2024	31st Dec 2028
66802044	PICO 14 10x40cm CTN1	CE 00356	26 <sup>th</sup> May 2024	31st Dec 2028
66802045	PICO 14 15x15cm CTN1	CE 00356	26 <sup>th</sup> May 2024	31st Dec 2028
66802046	PICO 14 15x20cm CTN1	CE 00356	26 <sup>th</sup> May 2024	31st Dec 2028
66802047	PICO 14 15x30cm CTN1	CE 00356	26 <sup>th</sup> May 2024	31st Dec 2028
66802048	PICO 14 20x20cm CTN1	CE 00356	26 <sup>th</sup> May 2024	31st Dec 2028
66802049	PICO 14 25x25cm CTN1	CE 00356	26 <sup>th</sup> May 2024	31st Dec 2028
66771359	RENASYS Dressing Kit with Soft Port Small Kit	CE 00356	26 <sup>th</sup> May 2024	31st Dec 2028
66771360	RENASYS Dressing Kit with Soft Port Medium Kit	CE 00356	26 <sup>th</sup> May 2024	31st Dec 2028
66771361	RENASYS Dressing Kit with Soft Port Large Kit	CE 00356	26 <sup>th</sup> May 2024	31st Dec 2028
66771362	RENASYS Dressing Kit with Soft Port X-Large Kit	CE 00356	26 <sup>th</sup> May 2024	31st Dec 2028
02436	Dressing Non-Adherent 3"x3"	CE 00356	26 <sup>th</sup> May 2024	31st Dec 2028
02437	Dressing Non-Adherent 3"x8"	CE 00356	26 <sup>th</sup> May 2024	31st Dec 2028
66800980	RENASYS AB Abdominal Dressing Kit with Soft Port	CE 00356	26 <sup>th</sup> May 2024	31st Dec 2028
66800794	RENASYS-F Foam Dressing Kit with Soft Port Small Kit (10 x 8 x 3cm / 3.9 x 3.1 x 1.2in)	CE 00356	26 <sup>th</sup> May 2024	31st Dec 2028
66800795	RENASYS-F Foam Dressing Kit with Soft Port Medium Kit (20 x 12.5 x 3cm / 7.9 x 4.9 x 1.2in)	CE 00356	26 <sup>th</sup> May 2024	31st Dec 2028
66800796	RENASYS-F Foam Dressing Kit with Soft Port Large Kit (25 x 15 x 3cm / 9.8 x 5.9 x 1.2in)	CE 00356	26 <sup>th</sup> May 2024	31st Dec 2028
66800797	RENASYS-F Foam Dressing Kit with Soft Port X-Large Kit (48 x 41 x 1.5cm / 18.9 x 16.1 x 0.6in)	CE 00356	26 <sup>th</sup> May 2024	31st Dec 2028
66801253	RENASYS 15Fr Channel Drain Accessory Kit	CE 00356	26 <sup>th</sup> May 2024	31st Dec 2028
66801252	RENASYS 10mm Flat Drain Accessory Kit	CE 00356	26 <sup>th</sup> May 2024	31st Dec 2028

<b>Catalog Item</b>	<b>Description</b>	<b>Certificate number</b>	<b>Expiry date on the certificate</b>	<b>Extended expiry date</b>
66801251	RENASYS 10Fr Round Drain Accessory Kit	CE 00356	26 <sup>th</sup> May 2024	31st Dec 2028
66801254	RENASYS 19Fr Round Drain Accessory Kit	CE 00356	26 <sup>th</sup> May 2024	31st Dec 2028
66800799	RENASYS Soft Port	CE 00356	26 <sup>th</sup> May 2024	31st Dec 2028
66800853	RENASYS X-Large Transparent Film Dressing Kit	CE 00356	26 <sup>th</sup> May 2024	31st Dec 2028
66802134	RENASYS TOUCH Negative Pressure Wound Therapy	CE 00356	26 <sup>th</sup> May 2024	31st Dec 2028

**Smith & Nephew Medical Limited**

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## STATEMENT

We confirm that RENASYS TOUCH is suitable for connection to the 230V / 50 Hz electrical network. The kit includes a power cable for the device. The plug is adapted for rosettes used in Lithuania.

Disposable RENASYS tools listed below are suitable for the treatment of wounds under RENASYS TOUCH Negative Pressure Wound Therapy.

66801273	RENASYS TOUCH 300ml Canister with Solidifier
66801274	RENASYS TOUCH 800ml Canister with Solidifier
66800796	RENASYS-F Foam Dressing Kit - Large
66800795	RENASYS-F Foam Dressing Kit - Medium
66800794	RENASYS-F Foam Dressing Kit - Small
66800971	RENASYS Y-Connector
66800394	RENASYS Transparent Film Dressing
66802134	RENASYS TOUCH Non-Connect 4th Ed Device
66800799	RENASYS Soft Port
66801277	RENASYS TOUCH Carry Bag
66801276	RENASYS TOUCH Carry Strap

DocuSigned by:  
*Sam Atkinson*  
 Signer Name: Sam Atkinson  
Signing Reason: I approve this document  
Signing Time: 24-May-2024 | 09:49:55 BST  
4247BB1FEDB542C29087D6B268F91213

Signature:

Name: Sam Atkinson, Principal Regulatory Affairs Specialist

Date:24-MAY-2024

**Certificate Of Completion**

Envelope Id: 95B593B78A4E4C4C8EA201166D685078	Status: Completed
Subject: Complete with DocuSign: STATEMENT - RENASYS TOUCH - LITHUANIA.docx	
Source Envelope:	
Document Pages: 1	Signatures: 1
Certificate Pages: 2	Initials: 0
AutoNav: Enabled	Envelope Originator:
Enveloped Stamping: Enabled	Sam Atkinson
Time Zone: (UTC) Dublin, Edinburgh, Lisbon, London	TJ Smith & Nephew Limited
	101 Hesse Road
	Hull, Hull HU3 2BN
	sam.atkinson@smith-nephew.com
	IP Address: 216.222.214.6

**Record Tracking**

Status: Original 24-May-2024   09:06	Holder: Sam Atkinson sam.atkinson@smith-nephew.com	Location: DocuSign
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**Signer Events**

Sam Atkinson  
sam.atkinson@smith-nephew.com  
Principal Regulatory Affairs Specialist  
Security Level: Email, Account Authentication (Required)

**Signature**

*Sam Atkinson*

Signature Adoption: Pre-selected Style  
Signature ID:  
4247BB1F-EDB5-42C2-9087-D6B268F91213  
Using IP Address: 216.222.214.6

**Timestamp**

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**Status**

**Timestamp**

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**Timestamp**

**Notary Events**

**Signature**

**Timestamp**

**Envelope Summary Events**

**Status**

**Timestamps**

Envelope Sent	Hashed/Encrypted	24-May-2024   09:06
Envelope Updated	Security Checked	24-May-2024   09:49
Envelope Updated	Security Checked	24-May-2024   09:49
Certified Delivered	Security Checked	24-May-2024   09:49
Signing Complete	Security Checked	24-May-2024   09:49
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**Status**

**Timestamps**