


EUROPEAN DECLARATION OF CONFORMITY ¹

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

Manufacturer's Name³	Smith & Nephew Medical Limited
Business Address⁴	101 Hessle Road Hull, HU3 2BN United Kingdom
Single Registration Number (SRN) ⁵	TBD
European Authorised Representative⁶	Smith & Nephew Operations B.V.
Business Address⁷	Bolemlaan 2, 2132 NP Hoofddorp, Netherlands
Product Name⁸:	RENASYS Y-Connector
Intended Use⁹	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"> • Flaps and grafts (only in one wound configuration) • Open abdomen (only in one wound configuration & only with RENASYS TOUCH and RENASYS AB Abdominal Kit) • Chronic • Acute • Traumatic • Sub-Acute and dehiscent wounds • Ulcers (such as pressure or diabetic) • Partial-thickness burns
Conformity Assessment Procedure (Annex)¹⁰	Not applicable
Notified Body Name¹¹	Not applicable
Notified Body Number¹²	Not applicable
Verification Certificate(s)¹³	Not applicable

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

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

Standards / Common Specification(s) ²⁶ :		
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 ²⁷ :			
Language ²⁸		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 заздравяването 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"> • Ламба и присадки (само в конфигурация с една рана) • Отворени коремни рани (само в конфигурация с

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			<p>една рана и само с RENASYS TOUCH и абдоминален кит RENASYS AB)</p> <ul style="list-style-type: none"> • Хронични • Остри • Травматични • Субакутни и дехисцентни рани • Язви (като от натиск или диабетни) • Изгаряния с частична дебелина
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"> • reznjevi i graftovi (samo u konfiguraciji jedne rane) • otvoreni abdomen (samo u konfiguraciji jedne rane i samo s RENASYS TOUCH i abdominalnim kompletom RENASYS AB) • kronične • akutne • traumatske • subakutne i dehiscentne rane • ulcerozne (kao što su one uzrokovane tlakom ili dijabetesom) • opekline drugog stupnja.
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"> • laloky a štěpy (pouze při konfiguraci pro jednu ránu) • otevřené břicho (pouze u konfigurace pro jednu ránu a pouze se systémem RENASYS TOUCH a sadou RENASYS AB Abdominal Kit) • chronické • akutní • traumatické • subakutní rány a rány s dehiscencí • ulcerující (např. dekubity nebo diabetické rány) • popáleniny druhého stupně
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, sårkssudater 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"> • Lapper og grafts (kun i en konfiguration med ét sår) • Åbne abdominale (kun i en konfiguration med ét sår og kun med RENASYS TOUCH og RENASYS AB abdominalsæt) • Kroniske • Akutte • Traumatiske • Subakutte og rumperede sår • Sår i form af tryksår eller diabetiske sår • Delhudsforbrændinger
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"> • Lappen en transplantaten (alleen bij configuratie voor één wond) • Open abdomen (alleen bij configuratie voor één wond & alleen met RENASYS TOUCH en RENASYS AB abdominale kit) • Chronisch • Acuut • Traumatisch • Subacuut en wonden met dehiscentie • Zweren (zoals decubitus- of diabetische ulcera) • Tweedegraads brandwonden
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"> • nahalapid ja -siirikud (ainult ühe haava konfiguratsioonis) • avatud kõht (ainult ühe haava konfiguratsioonis ning ainult koos süsteemiga RENASYS TOUCH ja kõhukomplektiga RENASYS AB) • kroonilised • ägedad • traumaatilised • alaägedad ja irevil haavad • haavandid (näiteks lamatishaavandid või diabeetilised haavandid) • II astme põletused
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"> • ihokielekkeet ja ihonsiirteet (vain yhden haavan hoidossa) • avoin vatsa (vain yhden haavan hoidossa ja vain RENASYS TOUCH:in ja RENASYS AB - vatsapakkauksen kanssa) • krooninen • akuutti • traumaattinen • subakuutit ja auenneet haavat • haavaumat (kuten paine- tai diabeettiset haavat) • toisen asteen palovammat
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"> • lambeaux et greffes (uniquement en configuration à une seule plaie) • Abdomen ouvert (uniquement en configuration à une seule plaie et uniquement avec RENASYS TOUCH et le kit abdominal RENASYS AB) • Chroniques • Aiguës • Traumatiques • Plaies subaiguës et déhiscentes • Ulcères (comme les ulcères de pression ou diabétiques) • Brûlures au deuxième degré
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"> • Lappenplastiken und Transplantationswunden (nur bei der Konfiguration mit einer Wunde) • Offenes Abdomen (nur bei Konfigurationen mit

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			<p>einer Wunde und nur mit RENASYS TOUCH und RENASYS AB Abdominalkit)</p> <ul style="list-style-type: none"> • Chronische Wunden • Akute Wunden • Traumatische Wunden • Subakute und dehiszente Wunden • Ulzera (z. B. Druck- oder diabetischer Ulzerus) • Verbrennungen zweiten Grades
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"> • Κρημνοί και μοσχεύματα (μόνο με τη διαμόρφωση ενός τραύματος) • Ανοικτή κοιλιακή χώρα (μόνο με τη διαμόρφωση ενός τραύματος και μόνο με το RENASYS TOUCH και το κιτ κοιλιακής χώρας RENASYS AB) • Χρόνια τραύματα • Οξέα τραύματα • Τραύματα κακώσεων • Υποξέα τραύματα και τραύματα που έχουν διαρρηχθεί • Έλκη (όπως οι κατακλίσεις ή τα διαβητικά έλκη) • Εγκαύματα μερικού πάχους
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"> • lebenyek és graftok (csak egysebes konfigurációban) • nyílt hasi seb (csak egysebes konfigurációban és csak RENASYS TOUCH és RENASYS AB hasi készlettel) • krónikus • akut • traumás • szubakut és szétnyílt sebek • fekélyek (pl. nyomásos vagy diabetikus) • részleges mélységű égési sérülések
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"> • Lembi e innesti (solo nella configurazione per una ferita) • Addome aperto (solo nella configurazione per una ferita e solo con RENASYS TOUCH e kit addominali RENASYS AB) • Ferite croniche • Ferite acute • Ferite traumatiche • Ferite subacute e deiscenti • Ulcere (come quelle da pressione o diabetiche) • Ustioni a spessore parziale
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"> • lēveri un transplantāti (tikai vienas brūces konfigurācijā); • atvērta vēdera (tikai vienas brūces konfigurācijā un tikai ar RENASYS TOUCH un RENASYS AB vēdera dobuma komplektu); • hroniskas; • akūtas; • traumatiskas; • subakūtas un plēstas brūces; • čūlas (spiediena vai diabēta); • daļēja biezuma apdegumi.
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"> • lūpai ir transplantatai (tik vienos žaizdos konfigūracija); • atvirosios pilvo (tik vienos žaizdos konfigūracija ir tik su RENASYS TOUCH ir RENASYS AB pilvo rinkiniu); • lėtinės; • ūmios; • trauminės;

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			<ul style="list-style-type: none"> • apyūmēs arba žiojėjančios; • opos (sukeltos nuogulų ar diabeto); • dalinio storio nudegimai.
Polish	Polski	PL	<p>System RENASYS TOUCH jest wskazany do stosowania u pacjentów, którzy mogą odnieść korzyść z urzę dzenia odsysającego (podciś nieniowe leczenia ran), ponieważ system może 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"> • Płaty i przeszczepy (wyłą cznie w konfiguracji jednej rany) • Otwarta jama brzuszna (wyłą cznie w konfiguracji jednej rany i wyłą cznie z RENASYS TOUCH i zestawem brzuszny RENASYS AB) • Rany przewlekłe, • Rany ostre, • Rany urazowe, • Rany podostre i z rozchodzą cymi się brzegami, • Owrzodzenia (np. cukrzycowe lub odleż yny), • Oparzenia z czę ś ciowymi ranami głę bszymi,
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"> • Retalhos e enxertos (apenas configuração de uma ferida) • Abdómen aberto (apenas configuração de uma ferida e apenas com o RENASYS TOUCH e o kit abdominal RENASYS AB) • Crónica • Aguda • Traumática • Feridas subagudas e deiscências • Úlceras (como diabéticas ou de pressão) • Queimaduras de espessura parcial
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"> • Lambouri și grefe (doar în configurație cu o singură plagă) • Abdomen deschis (doar în configurație cu o singură plagă și doar cu RENASYS TOUCH și trusa abdominală RENASYS AB) • Cronice • Acute • Traumatische • Plăgi subacute și dehiscente • Ulcere (cum ar fi cele de decubit sau diabetice) • Arsuri de grosime parțială
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"> • neštepené transplantáty a štepy (iba v konfigurácii s jednou ranou) • otvorené abdominálne (iba v konfigurácii s jednou ranou a s RENASYS TOUCH a abdominálnou súpravou RENASYS AB) • chronické • akútne • úrazové • subakútne a dehiscentné rany • vrede (ako napr. tlakové alebo diabetické) • popáleniny čiastočnej hrúbky
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"> • zakrilca in grafti (samo pri konfiguraciji ene rane); • odprte trebušne rane (samo pri konfiguraciji ene rane in samo s sistemom RENASYS TOUCH in abdominalnim kompletom RENASYS AB); • kronične; • akutne; • poškodbene; • subakutne in razprte rane; • razjede (npr. preležaninske ali diabetične); • opekline druge stopnje.
Spanish	Español	ES	RENASYS TOUCH está indicado para pacientes que

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			<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"> • Colgajos e injertos (solo en configuración de una herida) • Abdomen abierto (solo en configuración de una herida y solo con el RENASYS TOUCH y el kit abdominal RENASYS AB) • Crónica • Aguda • Traumática • Heridas subagudas y con dehiscencia • Úlceras (como las úlceras por presión o las diabéticas) • Quemaduras de espesor parcial
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"> • lambåer och grafter (endast för konfigurering av ett sår) • öppna abdominalsår (endast för konfigurering av ett sår & endast med with RENASYS TOUCH och RENASYS AB abdominalkit) • kroniska • akuta • traumatiska • subakuta och rupturerade sår • diabetessår och trycksår • delhudsbrännskador

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.

Smith and Nephew Medical Limited
101 Hessle Road
Hull
HU3 2BN
United Kingdom

14 May 2024

Notified Body Confirmation Letter
Reference: EU2023-607/856460

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, **BSI Group The Netherlands B.V.**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **2797** on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Smith and Nephew Medical Limited
101 Hessle Road
Hull
HU3 2BN
United Kingdom
SRN Number: GB-MF-000017580

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR

application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of BSI Group The Netherlands B.V.,



Graeme Tunbridge
Senior Vice President, Medical Devices

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
ACTICOAT Flex 3 Basic UDI-DI: 5000223SN000154RG	Class III	N/A	MDD Certificate #1: CE 00356 Expiry date: 26/05/2024 NB#: 2797 MDD Certificate #2: CE 547893 Expiry date: 26/05/2024 NB#: 2797
ACTICOAT Flex 7 Basic UDI-DI: 5000223SN000153RE	Class III	N/A	MDD Certificate #1: CE 00356 Expiry date: 26/05/2024 NB#: 2797 MDD Certificate #2: CE 544419 Expiry date: 26/05/2024 NB#: 2797
ACTICOAT / ACTICOAT 3 Basic UDI-DI: 5000223SN000145RF	Class III	N/A	MDD Certificate #1: CE 00356 Expiry date: 26/05/2024 NB#: 2797 MDD Certificate #2: CE 90692 Expiry date: 26/05/2024 NB#: 2797
ACTICOAT 7 Basic UDI-DI: 500223SN000146RH	Class III	N/A	MDD Certificate #1: CE 00356 Expiry date: 26/05/2024 NB#: 2797 MDD Certificate #2: CE 90692 Expiry date: 26/05/2024 NB#: 2797
Iodosorb Powder Basic UDI-DI: 500223SN000147RK	Class III	N/A	MDD Certificate #1: CE 00356 Expiry date: 26/05/2024 NB#: 2797 MDD Certificate #2: CE 511078 Expiry date: 26/05/2024 NB#: 2797
Iodosorb Dressing Basic UDI-DI: 500223SN000149RP	Class III	N/A	MDD Certificate #1: CE 00356 Expiry date: 26/05/2024 NB#: 2797 MDD Certificate #2: CE 511078 Expiry date: 26/05/2024 NB#: 2797

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Iodosorb Ointment Basic UDI-DI: 500223SN000148RM	Class III	N/A	MDD Certificate #1: CE 00356 Expiry date: 26/05/2024 NB#: 2797 MDD Certificate #2: CE 511078 Expiry date: 26/05/2024 NB#: 2797
Bactigras Basic UDI-DI: 5000223SN000144RD	Class III	N/A	MDD Certificate #1: CE 00356 Expiry date: 26/05/2024 NB#: 2797 MDD Certificate #2: CE 01105 Expiry date: 26/05/2024 NB#: 2797
Allevyn Non-adhesive Basic UDI-DI: 5000223SN000128RF	Class IIb excluding Class IIb implantable non-WET	N/A	MDD Certificate #1: CE 00356 Expiry date: 26/05/2024 NB#: 2797
Allevyn Gentle Basic UDI-DI: 5000223SN000170RE	Class IIb excluding Class IIb implantable non-WET	N/A	MDD Certificate #1: CE 00356 Expiry date: 26/05/2024 NB#: 2797
Allevyn Adhesive Basic UDI-DI: 5000223SN000127RD	Class IIb excluding Class IIb implantable non-WET	N/A	MDD Certificate #1: CE 00356 Expiry date: 26/05/2024 NB#: 2797
RENASYS AB Abdominal Kit Basic UDI-DI: 5000223SN000137RG	Class IIb excluding Class IIb implantable non-WET	N/A	MDD Certificate #1: CE 00356 Expiry date: 26/05/2024 NB#: 2797
RENASYS-F Foam Dressing kit with Soft Port and Transparent Film Basic UDI-DI: 5000223SN000172RJ	Class IIb excluding Class IIb implantable non-WET	N/A	MDD Certificate #1: CE 00356 Expiry date: 26/05/2024 NB#: 2797
RENASYS Gauze Dressing kits RENASYS Drain Dressing kits Basic UDI-DI: 5000223SN000161RD	Class IIb excluding Class IIb implantable non-WET	N/A	MDD Certificate #1: CE 00356 Expiry date: 26/05/2024 NB#: 2797
RENASYS Drain Accessory kits	Class IIb excluding Class IIb implantable non-WET	N/A	MDD Certificate #1: CE 00356 Expiry date: 26/05/2024

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Basic UDI-DI: 5000223SN000162RF			NB#: 2797
RENASYS TOUCH Non-Connect Basic UDI-DI: 5000223SN000138RJ	Class IIb excluding Class IIb implantable non-WET	N/A	MDD Certificate #1: CE 00356 Expiry date: 26/05/2024 NB#: 2797
PROFORE Multi-Layer Bandage System Basic UDI-DI: 5000223SN000131R4	Class IIb excluding Class IIb implantable non-WET	N/A	MDD Certificate #1: CE 00356 Expiry date: 26/05/2024 NB#: 2797
Intrasite Conformable Basic UDI-DI: 5000223SN000129RH	Class IIb excluding Class IIb implantable non-WET	N/A	MDD Certificate #1: CE 00356 Expiry date: 26/05/2024 NB#: 2797
PICO 7 / PICO 7Y / PICO 14 Basic UDI-DI: 5000223SN000135RC	Class IIb excluding Class IIb implantable non-WET	N/A	MDD Certificate #1: CE 00356 Expiry date: 26/05/2024 NB#: 2797
Versajet III console Basic UDI-DI: 5000223SN000176RS	Class IIb excluding Class IIb implantable non-WET	Versajet II console	MDD Certificate #1: CE 00356 Expiry date: 26/05/2024 NB#: 2797
Versajet III foot switch Basic UDI-DI: 5000223SN000177RU	Class IIb excluding Class IIb implantable non-WET	Versajet II foot switch	MDD Certificate #1: CE 00356 Expiry date: 26/05/2024 NB#: 2797
Versajet III handpiece Basic UDI-DI: 5000223SN000175RQ	Class IIa	Versajet II handpiece	MDD Certificate #1: CE 00356 Expiry date: 26/05/2024 NB#: 2797
Solosite Basic UDI-DI: 5000223SN000125R9	Class IIa	N/A	MDD Certificate #1: CE 00356 Expiry date: 26/05/2024 NB#: 2797
Cuticerin Jelonet Plus Basic UDI-DI: 5000223SN000118RC	Class IIa	N/A	MDD Certificate #1: CE 00356 Expiry date: 26/05/2024 NB#: 2797
Proshield Plus Basic UDI-DI: 5000223SN000159RS	Class IIa	N/A	MDD Certificate #1: CE 00356 Expiry date: 26/05/2024 NB#: 2797

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Proshield Foam & Spray Basic UDI-DI: 5000223SN000160RB	Class IIa	N/A	MDD Certificate #1: CE 00356 Expiry date: 26/05/2024 NB#: 2797
Opsite Spray Basic UDI-DI: 5000223SN000111QW	Class IIa	N/A	MDD Certificate #1: CE 00356 Expiry date: 26/05/2024 NB#: 2797
SECURA No-Sting Barrier Film Basic UDI-DI: 5000223SN000124R7	Class IIa	N/A	MDD Certificate #1: CE 00356 Expiry date: 26/05/2024 NB#: 2797
Skin Prep Basic UDI-DI: 5000223SN000168RT	Class IIa	N/A	MDD Certificate #1: CE 00356 Expiry date: 26/05/2024 NB#: 2797

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	Action
2024/05/14	Initial issue



By Royal Charter

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.

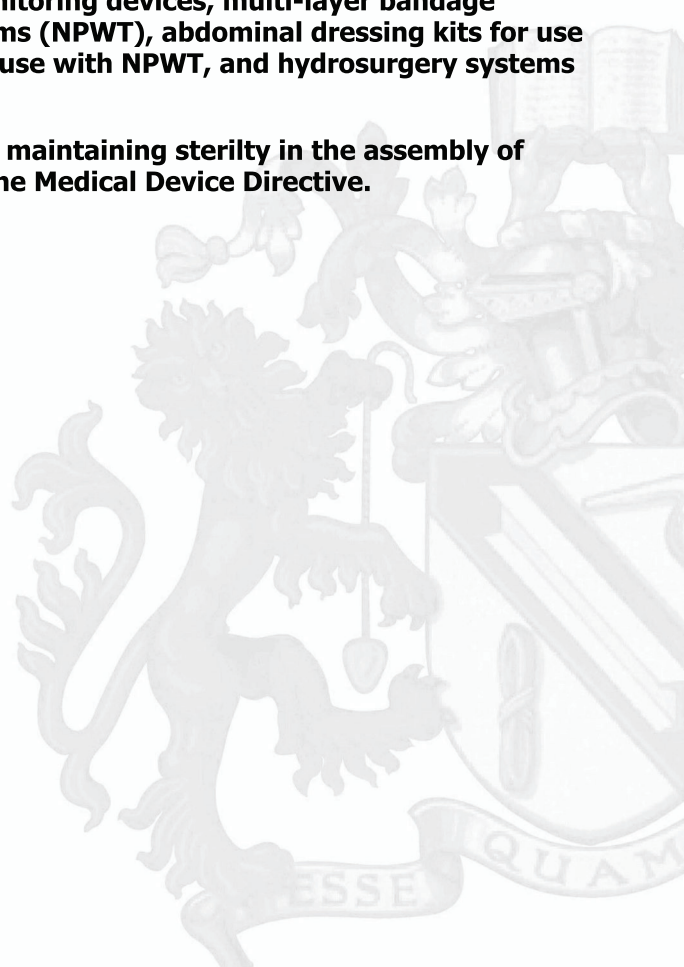
Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780
BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.
A member of BSI Group of Companies.

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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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
Class III		
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

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

Date: **2020-01-31**

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

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Page 3 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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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
Class IIb		
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

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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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
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**

Date: **2020-01-31**

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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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
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**Date: **2020-01-31**Expiry Date: **2024-05-26**

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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.
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
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

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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BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.
A member of BSI Group of Companies.



By Royal Charter

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
Class IIa		
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	--

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

Date: **2020-01-31**

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

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Page 8 of 8

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BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.
A member of BSI Group of Companies.

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 Hessle 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
101 Hessle Road
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F: + 44 (0)1482 328326
www.smith-nephew.com

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 FELEUSON

Position :

SENIOR REGULATORY AFFAIRS MANAGER

Signed :



Dated :

04 NOV 2021

Certificate Reference :

HU/110 issue 12

Smith & Nephew Medical Limited
 101 Hessle Road
 Hull
 HU3 2BN
 England

T: + 44 (0)1482 225181
 F: + 44 (0)1482 328326
 www.smith-nephew.com



EUROPEAN DECLARATION OF CONFORMITY¹

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

Manufacturer's Name³	Smith & Nephew Medical Limited
Business Address⁴	101 Hessle Road, Hull, HU3 2BN, United Kingdom
Single Registration Number (SRN)⁵	GB-MF-000017580
European Authorised Representative⁶	Smith & Nephew Operations B.V.
Business Address⁷	Bloemlaan 2, 2132 NP Hoofddorp, Netherlands
Product Name: (see attached schedule for product codes/catalogue numbers) ⁸	RENASYS Touch Canisters
Intended Use⁹ See table for other languages	Intended to be used in conjunction with Smith & Nephew Negative Pressure Wound Therapy (NPWT) systems.
Conformity Assessment Procedure (Annex)¹⁰	N/A
Notified Body Name¹¹	N/A
Notified Body Number¹²	N/A
Verification Certificate(s)¹³	N/A

Signed on behalf of Smith & Nephew Medical Limited¹⁴

Signature¹⁵	DocuSigned by:   Signer Name: Ken Fergusson Signing Reason: I approve this document Signing Time: 07-Apr-2022 17:58:17 BST 70CA089D3CF744E288FB372950E2A83E
Name¹⁶	Ken Fergusson

Smith & Nephew Medical Limited

101 Hessle Road
Hull
HU3 2BN
England

T: + 44 (0)1482 225181
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www.smith-nephew.com



Position¹⁷	Senior Regulatory Affairs Manager
Date¹⁸	07-Apr-2022 17:58:33 BST
Location¹⁹	Hull
Declaration of Conformity Reference²⁰	DOC-WMTF-005/V2

Product Schedule²¹

Product Code / Catalogue Number²²	Product Description or Product Variant²³	Risk Classification²⁴	Basic UDI²⁵
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 Number²⁷

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

Smith & Nephew Medical Limited
 101 Hessle Road
 Hull
 HU3 2BN
 England

T: + 44 (0)1482 225181
 F: + 44 (0)1482 328326
 www.smith-nephew.com

Smith+Nephew

Intended Use European Language Translations²⁸:

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

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Language ²⁹	Code	No.	Translated Terms
Bulgarian:	BG	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 (ERN)
		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

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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 ²⁹	Code	No.	Translated Terms
Croatian:	HR	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 proizvoda: (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

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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 ²⁹	Code	No.	Translated Terms
Czech:	CZ	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 označeného subjektu
		12	Číslo označeného 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



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



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Language ²⁹	Code	No.	Translated Terms
Danish:	DK	1	EUROPÆISK OVERENSSTEMMELSESESKLÆRING
		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	Tilsligtet 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

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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 ²⁹	Code	No.	Translated Terms
Dutch:	NL	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 ²⁹	Code	No.	Translated Terms
Estonian:	EE	1	EUROOPA VASTAVUSDEKLARATSIION
		2	Selle deklaratsiooniaga 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

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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 ²⁹	Code	No.	Translated Terms
Finnish:	FI	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

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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 ²⁹	Code	No.	Translated Terms
French:	FR	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 ²⁹	Code	No.	Translated Terms
German	DE	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

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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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Language ²⁹	Code	No.	Translated Terms
Greek:	GR	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

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

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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 ²⁹	Code	No.	Translated Terms
Italian:	IT	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	Uso previsto: traduzioni nelle lingue europee
	29	Lingua



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Language ²⁹	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 ²⁹	Code	No.	Translated Terms
Lithuanian:	LT	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 Igaliotasis 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 istaigos vardas
		12	Notifikuotosios istaigos 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



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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 ²⁹	Code	No.	Translated Terms
Polish:	PO	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 ²⁹	Code	No.	Translated Terms
Portuguese:	PT	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 ²⁹	Code	No.	Translated Terms
Romanian:	RO	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



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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 ²⁹	Code	No.	Translated Terms
Slovak:	SK	1	VYHLÁSENIE O ZHODE EÚ
		2	Vyhlasenie 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

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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 ²⁹	Code	No.	Translated Terms
Slovenian:	SL	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 priglšenega organa
		12	Številka priglšenega 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



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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 ²⁹	Code	No.	Translated Terms
Spanish:	ES	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 ²⁹	Code	No.	Translated Terms
Swedish:	SE	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

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	26	Standard/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 2nd 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:

Ken Fergusson



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 ¹


Declaration confirms that the product listed below meets: Regulation 2017/745 and is issued under the sole responsibility of Smith & Nephew Medical Limited².

Manufacturer's Name³	Smith & Nephew Medical Limited
Business Address⁴	101 Hessle Road, Hull, HU3 2BN, United Kingdom
Single Registration Number (SRN) ⁵	GB-MF-000017580
European Authorised Representative⁶	Smith & Nephew Operations B.V.
Business Address⁷	Bloemlaan 2, 2132 NP Hoofddorp, Netherlands
Product Name⁸:	OPSITE/APPLICA
Intended Use⁹	OPSITE film is indicated for: <ul style="list-style-type: none"> • Use as an incision drape in surgical procedures • Superficial wounds (e.g., minor burns, scalds, abrasions, and lacerations) • Split-thickness skin graft donor sites • Closed surgical wounds • Fixation of devices to the skin (i.e., catheters, tubing, primary dressings)
Conformity Assessment Procedure (Annex)¹⁰	Annex XI Part A (Production Quality Assurance)
Notified Body Name¹¹	BSI Group The Netherlands B.V
Notified Body Number¹²	No. 2797
Verification Certificate(s)¹³	MDR 737173

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Signed on behalf of Smith & Nephew Medical Limited ¹⁴	
Signature¹⁵	<p>DocuSigned by:</p> <p><i>Amrita Butler</i></p> <p> Signer Name: Amrita Butler Signing Reason: I approve this document Signing Time: 14-Apr-2023 11:33:08 BST C4EE3BFE6D3C4D78A1A614BF7DD28AA1</p>
Name¹⁶	Amrita Butler
Position¹⁷	Senior Regulatory Affairs Manager
Date¹⁸	14-Apr-2023 11:33:44 BST
Location¹⁹	Hull, UK
Declaration of Conformity Reference²⁰	DOC-WMTF-024/V2

Product Schedule ²¹			
Product Code / Catalogue Number ²²	Product Description or Product Variant ²³	Risk Classification ²⁴	Basic UDI ²⁵
4542	OPSITE - 28x10cm	IIa	5000223SN000114R4
4963	OPSITE - 14x10cm	IIa	5000223SN000114R4
4967	OPSITE - 14x25cm	IIa	5000223SN000114R4
4975	OPSITE - 10x14cm	IIa	5000223SN000114R4
4986	OPSITE - 15x28cm	IIa	5000223SN000114R4
4987	OPSITE - 28x30cm	IIa	5000223SN000114R4
4988	OPSITE - 28x45cm	IIa	5000223SN000114R4
4989	OPSITE - 55x45cm	IIa	5000223SN000114R4
4994	OPSITE - 84x56cm	IIa	5000223SN000114R4
4995	OPSITE - 42x40cm	IIa	5000223SN000114R4
66001217	APPLICA - 10x20cm	IIa	5000223SN000114R4
66001218	APPLICA - 20x30cm	IIa	5000223SN000114R4
66001219	APPLICA - 28x30cm	IIa	5000223SN000114R4
66001220	APPLICA - 35x45cm	IIa	5000223SN000114R4
66001221	APPLICA - 45x60cm	IIa	5000223SN000114R4
66001222	APPLICA - 56x84cm	IIa	5000223SN000114R4

Standards / Common Specification(s) ²⁶ :
EN ISO 780:2015
EN ISO 13485:2016/A11:2021

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EN ISO 15223-1:2021
EN ISO 14971:2019/A11:2021
ISO 10993-1:2018
ISO 10993-3:2014
ISO 10993-5:2009
ISO 10993-7:2008/A1:2019
ISO 10093-10:2021
ISO 10993-18:2020
EN ISO 20417:2021
EN 62366-1:2015/AMD1:2020
EN 556-1:2001/AC:2006
EN ISO 14644-1:2015
EN ISO 11607-1:2017
EN ISO 11607-2:2017
EN 13726-2:2002
EN 13726-3:2003
BS EN ISO 11135:2014
BS EN ISO 11737-1:2018/A1:2021
BS EN ISO 11737-2:2020
ISTA 2A

Intended Use European Language Translations²⁷:

Language ²⁸		Code	Intended Use
EN	Local		
Bulgarian	български език	BG	OPSITE е показан за: Употреба като покритие на разрези при хирургични операции, Повърхностни рани (напр. леки изгаряния, опарвания, ожулвания и разкъсвания), Донорски места на разцепена кожна присадка, Затворени хирургични рани, Фиксиране на устройства към кожата (т.е. катетри, тръбички, първични превръзки).
Croatian	Hrvatski	HR	Folija OPSITE indicirana je za: Uporabu kao incizijska folija u kirurškim zahvatima, Površinske rane (npr. manje opekline, ogrebotine i poderotine), Donorska mjesta transplantata djelomične debljine kože, Zatvorene kirurške rane, Pričvršćivanje uređaja na kožu (tj. kateteri, cijevi, primarne obloge).
Czech	Český Jazyk	CZ	OPSITE je indikováno pro: Použití jako rouška incize u chirurgických zákroků, Povrchové rány (např. drobné popáleniny, opáření, odřeniny a tržné rány), Dárcovská místa dermoepidermálního štěpu, Uzavřené chirurgické rány, Fixace zařízení na kůži (např. katetry, hadičky, primární krytí).

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Danish	Dansk	DK	OPSITE er indiceret til: Brug som incisionsafdækning under kirurgiske indgreb, Overfladiske sår (f.eks. mindre forbrændinger, skoldninger, hudafskrabninger og snitsår), Donorsteder for hudgrafter af delvis tykkelse, Lukkede operationssår, Fiksering af udstyr til huden (dvs. katetre, slanger, primære bandager).
Dutch	Nederlands	NL	OPSITE is voorgeschreven voor: Gebruik als afdek materiaal voor de incisie tijdens chirurgische procedures, Oppervlakkige wonden (bijv. eerstegraads brandwonden, brandplekken, schaafwonden en snijwonden), Split thickness-huidtransplantaten, Afgedichte chirurgische wonden, Fixatie van hulpmiddelen op de huid (bijv. katheters, slangen, primaire verbanden).
Estonian	Eesti	EE	Toote OPSITE näidustused: Kasutamiseks sisselõikekattena kirurgilistel protseduuridel, Pindmised haavad (nt pindmised põletused, põletushaavad, marrastused ja rebendid), Poolitatud paksusega nahasiiriku doonorkohad, Suletud kirurgilised haavad, Seadmete nahale kinnitamiseks (nt kateetrid, torud, primaarsed haavasidemed).
Finnish	Suomi	FI	OPSITE on tarkoitettu käytettäväksi seuraavasti: Käytä leikkausliinana kirurgisissa toimenpiteissä, Pinnallisiin haavoihin (esim. lievät palovammat, hiertymät ja repeämät), Osaihoiirteiden ihonottokohtiin, Suljettuihin kirurgisiin haavoihin, Laitteiden kiinnitys ihoon (eli katetrit, letkut, ensisijaiset sidokset).
French	Français	FR	OPSITE est indiqué pour : Usage de champ d'incision dans les interventions chirurgicales, Plaies superficielles (p. ex. brûlures légères, brûlures par liquide bouillant, abrasions et lacerations), Sites donneurs de greffe de peau mince, laies chirurgicales fermées, Fixation de dispositifs sur la peau (c'est-à-dire cathéters, tubulures, pansements primaires).
German	Deutsch	DE	OPSITE ist für Folgendes indiziert: Verwendung als Inzisionsabdeckung bei chirurgischen Eingriffen, Oberflächliche Wunden (z.B. leichte Verbrennungen, Verbrühungen, Schürf- und Schnittwunden), Entnahmestellen zur Spalthauttransplantation, Geschlossene Operationswunden, Fixierung von Produkten an der Haut (z. B. Katheter, Schläuche, Primärverbände) APPLICA ist indiziert für: Verwendung als Inzisionsabdeckung bei chirurgischen Eingriffen, Oberflächliche Wunden (z.B. leichte Verbrennungen, Verbrühungen, Schürf- und Schnittwunden), Entnahmestellen zur Spalthauttransplantation, Geschlossene Operationswunden, Fixierung von Produkten an der Haut (z.B. Katheter, Schläuche, Primärverbände).
Greek	Ελληνικά	GR	Η μεμβράνη OPSITE ενδείκνυται για τα εξής: Χρησιμοποιείται ως κάλυμμα τομής στις χειρουργικές διαδικασίες, Σε επιφανειακά τραύματα (π.χ. ελαφρά τραύματα, καψίματα, αμυχές και εκδορές), Σε σημεία του δέρματος μετά από λήψη δερματικού μοσχεύματος μερικού πάχους, Σε κλειστά χειρουργικά τραύματα, Για στερέωση συσκευών στο δέρμα (δηλ. καθετήρες, σωληνώσεις, κύρια επιθέματα).
Hungarian	Magyar	HU	Az OPSITE használata a következőkhöz javallt: Bemetszési izolálókendőként használható műtéti eljárások során, Felületi sebek (pl. enyhe égési sérülések, forrázások, horzsolások és szakadások) esetén, Részleges vastagságú bőrátültetési donorterületekhez, Zárt műtéti sebekhez, Eszközök (azaz katéterek, csövek, elsődleges kötszerek) rögzítéséhez a bőrön.
Italian	Italiano	IT	OPSITE è indicata per: L'utilizzo come telo per incisione nelle procedure chirurgiche, Ferite superficiali (ad es. ustioni minori, scottature, abrasioni e lacerazioni), Siti donatori per innesti cutanei a spessore parziale, Ferite chirurgiche chiuse, Fissaggio di dispositivi sulla cute (cioè cateteri, tubi, medicazioni primarie).
Latvian	Latviešu	LV	OPSITE ir indicēts: lietošanai kā iegriezumā pārklājam ķirurģiskās procedūrās; virspusējām brūcēm (piem., nelieliem apdegumiem, applaucējumiem, nobrāzumiem un plēsumiem); dalīta biežuma ādas pārstādīšanas donorvietām; slēgtām ķirurģiskām brūcēm; ierīču piestiprināšanai pie ādas (t.i., katetriem, caurulēm, primāriem pārsienamajiem materiāliem).

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Lithuanian	Lietuvių	LT	Toliau nurodytos OPSITE indikacijos. Naudokite kaip pjūvio užklotą chirurginių procedūrų metu, Paviršinės žaizdos (pvz., nestiprūs nudegimai, nusiplikimai, įbrėžimai ir įplėšimai), Dalies odos storio transplantatų donorinės vietos, Uždarytos chirurginės žaizdos, Priemonių tvirtinimas prie odos (pvz., kateterių, vamzdelių, pirminių tvarsčių).
Norwegian	Norsk	NO	OPSITE er indikert for: Brukes som snittduk i kirurgiske prosedyrer, Håndtering av overfladiske sår (f.eks. mindre brannskader, skrubbsår og laserasjoner), Splitttykkelse av hudtransplanterte donorsteder, Lukkede operasjonssår, Fiksering av enheter til huden (f.eks. katetre, slanger, primærbandasjer).
Polish	Polski	PL	Produkt OPSITE jest przeznaczony do: stosowania jako osłona nacięć podczas zabiegów chirurgicznych, powierzchniowych ran (np. drobne oparzenia, oparzenia, otarcia i skaleczenia), miejsc dawcy przeszczepu skóry o różnej grubości, zamkniętych ran chirurgicznych, mocowań wyrobów do skóry (np. cewników, drenów, opatrunków pierwotnych)
Portuguese	Português	PT	OPSITE é indicado para: Utilize como campo cirúrgico de incisões em procedimentos cirúrgicos, A gestão de feridas superficiais (p.ex.: queimaduras ligeiras, escaldões, abrasões e lacerações), Locais de doação com enxertos de pele de espessura reduzida, Feridas cirúrgicas fechadas, Fixação de dispositivos à pele (p.ex.: cateteres, tubagem, pensos primários).
Romanian	Română	RO	OPSITE se recomandă pentru: Utilizare drept câmp chirurgical pentru incizii în procedurile chirurgicale, Leziuni superficiale (de ex., arsuri minore, opăririi, excoriații și laceratii), Locațiile prelevării grefei de piele cu grosime parțială, Plăgi chirurgicale închise, Fixarea dispozitivelor pe piele (adică, catetere, tuburi, pansamente primare).
Slovak	Slovenčina	SK	Fólia OPSITE je indikovaná na: použitie ako rúško pri chirurgických zákrokoch, povrchové rany (napr. menšie popáleniny, obareniny, odreniny a tržné rany), plochy použité na kožné štepy v celej hrúbke, uzavreté chirurgické rany, fixáciu pomôcok na koži (napr. katétre, hadičky, primárne krytie).
Slovenian	Slovenščina	SI	Film OPSITE je indiciran za: uporabo kot tkanina za incizije pri kirurških posegih; površinske rane (npr. lažje opekline, oparine, abrazije in ureznine); mesta odvzema kožnega presadka delne debeline kože; zaprte kirurške rane; pritrdjevanje pripomočkov na kožo (npr. katetri, cevje, primarne obloge).
Spanish	Español	ES	OPSITE está indicado: Como paño de incisión en intervenciones quirúrgicas, Para heridas superficiales (por ejemplo, quemaduras leves, escaldaduras, abrasiones y laceraciones), Para zonas donantes de injertos de piel de espesor parcial, Para heridas quirúrgicas cerradas, Para la fijación de dispositivos a la piel (como catéteres, tubos y apósitos primarios)
Swedish	Svenska	SE	OPSITE indiceras för: Användning som sårfilm vid kirurgiska ingrepp, Ytliga sår (t.ex. mindre brännskador, skållningsskador, abrasioner och lacerationer), Platser där hudgraft med delad tjocklek har tagits, Förslutna kirurgiska sår, Fixering av enheter på huden (t.ex. katetrar, slangar, primära förband).

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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	Maltese	Malti	MT
Appendix 16	Polish	Polski	PL
Appendix 17	Portuguese	Português	PT
Appendix 18	Romanian	Română	RO
Appendix 19	Slovak	Slovenčina	SK
Appendix 20	Slovenian	Slovenščina	SL
Appendix 21	Spanish	Español	ES
Appendix 22	Swedish	Svenska	SE

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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		

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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 OVERENSSTEMMELSESESRKLÆRING		
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	Tilsigtet 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	Tilsigtet 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: (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/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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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			

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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 beigegefügtetes 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		

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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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Appendix 11			
Language (EN)	Hungarian (HU)	Language (Local)	Magyar
No.	Translated Term		
1	EURÓPAI MEGFELELŐSÉGI NYILATKOZAT		
2	A nyilatkozat megerősíti, hogy az alább felsorolt termék megfelel a következőknek: A 2017/745 rendelet, [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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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		

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Appendix 15				
Language (EN)		Maltese (MT)	Language (Local)	Malti
No.	Translated Term			
1	DIKJARAZZJONI EWROPEA TA' KONFORMITÁ			
2	Id-dikjarazzjoni tikkonferma li l-prodott imnizzel hawn taht jissodisfa: Ir-Regolamenti 2017/745, [dahhal legizlazzjoni Ewropea rilevanti ohra kif applikabbli] u tinhareg taht ir-responsabbiltà unika tal-Isem Ġuridiku tal-Manifattura			
3	Isem tal-Manifattur			
4	Indirizz tan-Negojzu			
5	Numru ta' Reġistrazzjoni Uniku (SRN)			
6	Rappreżentant Ewropew Awtorizzat			
7	Indirizz tan-Negojzu			
8	Isem tal-Prodott: (ara l-iskeda mehmūza għall-kodiċijiet tal-prodott/numri tal-katalgu)			
9	Użu Maħsub: Ara t-tabella għal-lingwi l-oħrajn			
10	Proċedura tal-Evalwazzjoni tal-Konformità (Anness)			
11	Isem tal-Korp Notifikat			
12	Numru tal-Korp Notifikat			
13	Ċertifikat(i) ta' Verifika			
14	Iffirmat f'Isem l-Isem Ġuridiku tal-Manifattura			
15	Firma			
16	Isem			
17	Pożizzjoni			
18	Data			
19	Post			
20	Referenza tad-Dikjarazzjoni ta' Konformità			
21	Skeda tal-Prodott			
22	Kodiċi tal-Prodott / Numru tal-Katalgu			
23	Deskrizzjoni tal-Prodott jew Varjant tal-Prodott			
24	Klassifikazzjoni tar-Riskju			
25	UDI-DI Bażiku			
26	Standards / Speċifikazzjoni(jiet) Komuni			
27	Użu Maħsub Traduzzjonijiet tal-Lingwi Ewropej			
28	Lingwa			

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Appendix 16			
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		

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Appendix 17			
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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Appendix 18				
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	Locatie			
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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Appendix 19			
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		

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Appendix 20				
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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Appendix 21			
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		

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Appendix 22				
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			

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EUROPEAN DECLARATION OF CONFORMITY ¹

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

Manufacturer's Name³	Smith & Nephew Medical Limited
Business Address⁴	101 Hessle Road, Hull, HU3 2BN, United Kingdom
Single Registration Number (SRN) ⁵	GB-MF-000017580
European Authorised Representative⁶	Smith & Nephew Operations B.V.
Business Address⁷	Bloemlaan 2, 2132 NP Hoofddorp, Netherlands
Product Name⁸:	RENASYS Touch Carry Bag & Carry Strap RENASYS GO Carry Bag & Carry Strap
Intended Use⁹	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.
Conformity Assessment Procedure (Annex)¹⁰	Not applicable, the devices are Class I Non-Sterile.
Notified Body Name¹¹	N/A
Notified Body Number¹²	N/A
Verification Certificate(s)¹³	N/A

Signed on behalf of Smith & Nephew Medical Limited ¹⁴	
Signature¹⁵	 <p>DocuSigned by: Sam Atkinson Signer Name: Sam Atkinson Signing Reason: I approve this document Signing Time: 14-Dec-2023 15:06:11 GMT 4247BB1FEDB542C29087D6B268F91213</p>
Name¹⁶	Sam Atkinson
Position¹⁷	Regulatory Approval Manager
Date¹⁸	14-Dec-2023 15:06:43 GMT

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Location¹⁹	Hull, UK
Declaration of Conformity Reference²⁰	DOC-WMTF-006/V2

Product Schedule²¹			
Product Code / Catalogue Number²²	Product Description or Product Variant²³	Risk Classification²⁴	Basic UDI²⁵
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

Standards / Common Specification(s)²⁶:		
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		

Intended Use European Language Translations²⁷:			
Language²⁸		Code	Intended Use
EN	Local		
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-druk wondtherapie (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	Przeznaczony 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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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		

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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 OVERENSSTEMMELSESESKLÆRING			
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	Tilsigtet 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	Tilsigtet 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: (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/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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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			

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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		

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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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Appendix 11			
Language (EN)	Hungarian (HU)	Language (Local)	Magyar
No.	Translated Term		
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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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		

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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			

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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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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		

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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			

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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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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		

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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		

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By Royal Charter

EU Quality Assurance Certificate

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

MDR 737173 R000

Manufacturer: Smith & Nephew Medical Ltd

Address:

101 Hessle Road
Hull
HU3 2BN
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
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
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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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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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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.

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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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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).

Manufacturer's Name :	Smith & Nephew Medical Limited
Business Address:	101 Hessle Road, Hull, HU3 2BN, United Kingdom.
Authorised Representative :	Smith & Nephew Orthopaedics GmbH, Alemannenstraße 14, 78532 Tuttlingen, Germany
Medical Devices:	RENASYS-F Foam Dressing kit with Soft Port RENASYS Soft Port Foam Wound Dressing for use with PICO and RENASYS NPWT Systems
Classification:	Class IIb
GMDN Code and Term:	34059 – Wound dressing kit, medicated, sterile
Scope of Application:	All batches supplied to which the Declaration of Conformity Procedure has been applied.
Declaration:	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 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)
Standards Applied:	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	
Product Codes:	Code	Size
	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 Daglish

Position:

Regulatory Affairs Manager

Signed:

DocuSigned by:

Signer Name: Andrew Daglish
Signing Reason: I approve this document
Signing Time: 10-Apr-2024 | 19:11:00 BST
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Dated:

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

Certificate Reference:

HU/135 issue 017