

Smith & Nephew Orthopaedics AG
Oberneuhofstrasse 10D
6340 Baar
Switzerland

T +41 79 720 73 11
www.smith-nephew.com

 We are smith&nephew

To whom it may concern:

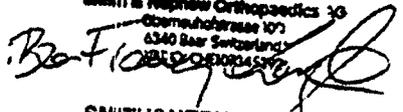
Baar, 17 March 2020

LETTER OF AUTHORIZATION

Smith & Nephew Orthopaedics AG, with offices in Oberneuhofstrasse 10 6340 Baar, Switzerland VAT number CHE 107345392 bank account 01005464001IBAN CH7187801001005464001 BIC DEUTCHZZ at DeutscheBankAG, represented by Bartomiej Zaręba in quality of Business Unit Manager.

As manufacturer of medical devices (hip and knee prostheses, trauma and endoscopy products) hereby confirm that our exclusive distributor for Lithuania is the company

OSTECA, UAB, with offices in Danes str. 47., Klaipeda – Lithuania, registration number 300871049, VAT no. LT100003238211, represented by Mr Arvydas Klovas in quality of General Director.


Smith & Nephew Orthopaedics AG
Oberneuhofstrasse 10D
6340 Baar Switzerland
BIC: DEUT3333
Name: Bartomiej Zaręba
Position: Business Unit Manager



Kopija tikra

OSTECA UAB
Name: Arvydas Klovas
Position: General Director

This authorization is valid for one year beginning with the signing date.

Smith&Nephew Orthopaedics AG
Oberneuhofstr. 10D
6340 Baar
Šveicarija

T +41 79 720 73 11
www.smith-nephew.com

Tam kam svarbu:

Kovo 17 d. 2020 m., Baar

ĮGALIOJIMAS

SMITH & NEPHEW Orthopaedics AG, kurios adresas yra Oberneuhofstr. 10D, Baar, Šveicarija, PVM kodas CHE107345392, banko sąskaita 0100546001IBAN CH7187801001005464001 SWIFT kodas DEUTCHZZ DeutscheBank AG, atstovaujama Verslo padalinio vadovo Bartlomieį Zareba

kaip medicininių prietaisų (klubo ir kelio endoprotezų, traumatologinių ir endoskopinių produktų) gamintojas

tokiu būdu patvirtina, kad išskirtinis distributorius Lietuvoje yra kompanija

UAB OSTECA, kurios adresas yra Danės g. 47, Klaipėda, Lietuva, registracijos numeris 300871049, PVM kodas LT100003238211, atstovaujama generalinio direktoriaus Arvydo Klovo.

Smith&Nephew Orthopaedics AG
Oberneuhofstr. 10D
6340 Baar
Šveicarija
PVM kodas CHE107345392

/Parašas/

Smith&Nephew
Vardas: Bartlomieį Zareba
Pareigos: Verslo padalinio vadovas

Osteca, UAB
Vardas: Arvydas Klovas
Pareigos: Generalinis direktorius

Šis įgaliojimas galioja vienerius metus, nuo jo pasirašymo datos.

Declaration of Conformity ENT and Joint Repair Class I Sterile Devices	Document Number:	95004
	Revision:	J
	ECN:	81102
	Page:	1 of 3

Manufacturer's Name & Address: ArthroCare Corporation
7000 West William Cannon Drive
Austin, TX 78735 USA

Manufacturing Facility(s): ArthroCare Corporation
7000 West William Cannon Drive
Austin, Texas 78735 USA

ArthroCare Corporation B32.1, St2, Zona Franca Coyol Coyol, Costa Rica, 20101 Costa Rica	ArthroCare Corporation 2301 E Saint Elmo Rd Suite 110 Austin, Texas 78744 USA
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European Authorized Representative: Smith & Nephew Orthopaedics GmbH
Alemannenstraße 14
78532 Tuttlingen
Germany
ec.rep@smith-nephew.com

Relevant Notified Body Number: CE0123

CE Certificate No. G2S 077112 0041, Rev. 00, Exp. 26 May 2024

Design Examination Certificate Number N/A Class 1 Sterile Devices

Validity Date: ----

Expiration Date: ----

ARTHROCARE/SMITH & NEPHEW HEREWITH DECLARES UNDER OUR SOLE RESPONSIBILITY THAT THE PRODUCTS MENTIONED IN THIS DECLARATION OF CONFORMITY MEET THE PROVISIONS OF THE FOLLOWING COUNCIL DIRECTIVES:

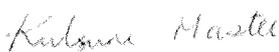
- 93/42/EEC FOR MEDICAL DEVICES, AS AMENDED BY 2007/47/EC

ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER.

Notified Body Address: TÜV SÜD Product Service GmbH
Zertifizierstelle
Ridlerstrasse 65
80339 München
Germany

Location Issued: Austin, Texas USA

Date Issued: 17 Feb 2020

Signature: 

Name: Kulsum Master

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Declaration of Conformity ENT and Joint Repair Class I Sterile Devices	Document Number:	95004
	Revision:	J
	ECN:	81102
	Page:	2 of 3

Title: Director, Regulatory Affairs

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Declaration of Conformity ENT and Joint Repair Class I Sterile Devices		Document Number:	95004
		Revision:	J
		ECN:	81102
		Page:	3 of 3

Catalogue Number	Labeled Name	Technical File #	EU Device Class	EU Device Rule	Conformity Assessment per MDD		GMDN Code	Date of Initial CE Mark	Date of Obsolescence
					Annex	Section			
650-60100S	Ventura Sinus Dilation Balloon	TF-010	Class 1 Sterile	Rule 5	V	3	48140	12MAR2011	08MAY2019
19-1001	Ankle Distractor Strap	TF-43A	Class 1 Sterile	Rule 1	V	N/A	56637	28SEP2007	N/A
RR 300	Rapid Rhino® 3 cm Riemann Nasal Dressing	TF-22959	Class 1 Sterile	Rule 5	V	3	31919	08APR2008	N/A
RR 400	Rapid Rhino® 4 cm Riemann Nasal Dressing	TF-22959	Class 1 Sterile	Rule 5	V	3	31919	08APR2008	N/A
RR 450	Rapid Rhino® 4.5 cm Anterior	TF-22959	Class 1 Sterile	Rule 5	V	3	31919	08APR2008	N/A
RR 500	Rapid Rhino® 5.5 cm Goodman Nasal Dressing	TF-22959	Class 1 Sterile	Rule 5	V	3	12699	08APR2008	N/A
RR 530	Rapid Rhino® 5.5 cm Rapid-Pac	TF-22959	Class 1 Sterile	Rule 5	V	3	31919	08APR2008	N/A
RR 550	Rapid Rhino® 5.5 cm Anterior	TF-22959	Class 1 Sterile	Rule 5	V	3	31919	08APR2008	N/A
RR 551	Rapid Rhino® 5.5 cm Anterior Airway	TF-22959	Class 1 Sterile	Rule 5	V	3	12699	08APR2008	N/A
RR 552	Rapid Rhino® 5.5 cm Bilateral	TF-22959	Class 1 Sterile	Rule 5	V	3	12699	08APR2008	N/A
RR 555	Rapid Rhino® 5.5 cm Bilateral with Airway	TF-22959	Class 1 Sterile	Rule 5	V	3	12699	08APR2008	N/A
RR 600	Rapid Rhino® SINU-KNIT®	TF-22959	Class 1 Sterile	Rule 5	V	3	12699	08APR2008	N/A
RR 650	Rapid Rhino® SINU-FOAM® Dressing	TF-22959	Class 1 Sterile	Rule 5	V	3	31919	08APR2008	N/A
RR 750	Rapid Rhino® 7.5 cm Ant/Posterior	TF-22959	Class 1 Sterile	Rule 5	V	3	31919	08APR2008	N/A
RR 751	Rapid Rhino® 7.5 cm Ant/Posterior with Airway	TF-22959	Class 1 Sterile	Rule 5	V	3	12699	08APR2008	N/A
RR 752	Rapid Rhino® 7.5 cm Ant/Posterior Bilateral	TF-22959	Class 1 Sterile	Rule 5	V	3	12699	08APR2008	N/A
RR 755	Rapid Rhino® 7.5 cm Ant/Post Bilateral with Airway	TF-22959	Class 1 Sterile	Rule 5	V	3	12699	08APR2008	N/A
RR 800	Rapid Rhino® 8 cm Nasal Dressing	TF-22959	Class 1 Sterile	Rule 5	V	3	31919	08APR2008	N/A
RR 900	Rapid Rhino® Nasal Catheter Posterior Epistaxis	TF-22959	Class 1 Sterile	Rule 5	V	3	12699	06OCT2009	N/A
RR 1000	NASASTENT®	TF-45154	Class 1 Sterile	Rule 5	V	3	31919	21JUL2014	N/A

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Vertimas iš Anglų k.

**ATITIKTIES DEKLARACIJA
LOR IR SANARIŲ GYDYMO KLASĖ I STERILIOS PRIEMONĖS**

Dok. Nr.950045
Revizija: J
ECN: 81102
Psl.: 1 iš 3

Gamintojo pavadinimas & adresas: ArthroCare Corporation
7000 West William Cannon Drive
Austin, TX 78735 JAV
HU3 2BN

ArthroCare Corporation
7000 West William Cannon Drive
Austin, Teksasas 78735 JAV

Gamyba: ArthroCare Corporation
B32.1, St2, Zona Franca Coyol
Coyol Costa Rica, 20101
Costa Rica

ArthroCare Corporation
2301 E Saint Elmo Rd
Suite 110
Austin Texas 78744 JAV

Europos autorizavimo atstovai: Smith&Nephew Orthopedics GmbH
AlemannenStrasse 14
78532 Tutlingen
Vokietija
ec.rep@smith-nephew.com

Notifikuoto įstaigos numeris: CE0123

CE sertifikato Nr.: G2S 077112 0041, Rev. 00, Exp. 26 Gegužės 2024

Sertifikato patikrinimo N/A Klasė I Sterilios priemonės

Galiojimo data
Galiojimo pabaiga

ARTHROCARE/SMITH&NEPHEW PAŽYMI KAD PRODUKTAI IŠVARDINTI ŠIOJE ATITIKTIES DEKLARACIJOJE ATITINKA TOLESNĖS TARYBOS NUOSTATŲ DIREKTYVAS:

93/42/EEC MEDICININIUS PRIETAISUS, KAIP PATEIKTA PAGAL 2007/47/EC

VISA PAPILDOMA DOKUMENTACIJA YRA GAMINTOJO JURISDIKCIJOJE.

Notifikuotos įstaigos adresas: TUV SUD Product Servise GmbH
Zertifizierstelle
Ridlerstrasse 65
80339 Munichas
Vokietija

Išduota vieta: Austin, Teksasas JAV

Išdavimo data: 2020 Vasario 17 d.

Parašas: / /

Vardas: Kulsum Master

KONFIDENCIALUS IR TURTINIS

Šiame dokumente yra konfidenciali Smith&Nephew PLC ir Smith&Nephew, Inc. nuosavybės teise, priklausanti informacija, skirta naudoti, tik Smith&Nephew ir jo gamintojui. Ja negalima platinti ar dalintis visiškai ar iš dalies, be to, jo turinys jokia būdu, negali būti atskleistas be išankstinio be rašytinio Smith&Nephew leidimo, taip pat niekas nenaudos, kas prieštarautų išreikštiems ar numanomiems Smith&Nephew norams.

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**ATITIKTIES DEKLARACIJA
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Dok. Nr.950045

Revizija: J

ECN: 81102

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Pavadinimas:

Reguliavimo Reikalų Direktorius

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**ATTIKTIES DEKLARACIJA
LOR IR SANARIŲ GYDYMO KLASĖ I STERILIOS PRIEMONĖS**

Dok. Nr.950045
Revizija: J
ECN: 81102
Psl.: 3 iš 3

Kodas kataloge	Pavadinimas	Techninė byla	Priemonės klasė ES	Priemonės taisyklė ES	Priedas	Skyrus	GMDN kodas	ES gavimo data	Galiojimo pabaigos data
650-60100S	Ventura Sinus Dilation Baloon	TF-010	Klasė I Sterilus	Taisyklė 5	V	3	48140	12KOV2011	08GEG2019
19-1001	Ankle Distractor Strap	TF-43A	Klasė I Sterilus	Taisyklė 1	V	N/A	56637	28RUG2007	N/A
RR300	Rapid Rhino 3 cm Riemann Nasal Dressing	TF22959	Klasė I Sterilus	Taisyklė 5	V	3	31919	08BAL2008	N/A
RR400	Rapid Rhino 4 cm Riemann Nasal Dressing	TF22959	Klasė I Sterilus	Taisyklė 5	V	3	31919	08BAL2008	N/A
RR450	Rapid Rhino 4,5 cm Anterior	TF22959	Klasė I Sterilus	Taisyklė 5	V	3	12699	08BAL2008	N/A
RR500	Rapid Rhino 5,5 cm Goodman Nasal Dressing	TF22959	Klasė I Sterilus	Taisyklė 5	V	3	31919	08BAL2008	N/A
RR530	Rapid Rhino 5,5 cm Rapid-Pac	TF22959	Klasė I Sterilus	Taisyklė 5	V	3	31919	08BAL2008	N/A
RR550	Rapid Rhino 5,5 cm Anterior	TF22959	Klasė I Sterilus	Taisyklė 5	V	3	12699	08BAL2008	N/A
RR551	Rapid Rhino 5,5 cm Anterior Airway	TF22959	Klasė I Sterilus	Taisyklė 5	V	3	31919	08BAL2008	N/A
RR552	Rapid Rhino 5,5 cm Bilateral	TF22959	Klasė I Sterilus	Taisyklė 5	V	3	12699	08BAL2008	N/A
RR555	Rapid Rhino 5,5 cm Bilateral with Airway	TF22959	Klasė I Sterilus	Taisyklė 5	V	3	12699	08BAL2008	N/A
RR600	Rapid Rhino SINU-KNIT	TF22959	Klasė I Sterilus	Taisyklė 5	V	3	12699	08BAL2008	N/A
RR650	Rapid Rhino SINU-FOAM Dressing	TF22959	Klasė I Sterilus	Taisyklė 5	V	3	31919	08BAL2008	N/A
RR750	Rapid Rhino 7,5 cm Ant/Posterior	TF22959	Klasė I Sterilus	Taisyklė 5	V	3	31919	08BAL2008	N/A
RR751	Rapid Rhino 7,5 cm Ant/Posterior with Airway	TF22959	Klasė I Sterilus	Taisyklė 5	V	3	12699	08BAL2008	N/A
RR752	Rapid Rhino 7,5 cm Ant/Posterior Bilateral	TF22959	Klasė I Sterilus	Taisyklė 5	V	3	12699	08BAL2008	N/A
RR755	Rapid Rhino 7,5 cm Ant/Post Bilateral with Airway	TF22959	Klasė I Sterilus	Taisyklė 5	V	3	12699	08BAL2008	N/A
RR800	Rapid Rhino 8 cm Nasal Dressing	TF22959	Klasė I Sterilus	Taisyklė 5	V	3	12699	08BAL2008	N/A
RR900	Rapid Rhino Nasal Catheter Posterior Epistaxis	TF22959	Klasė I Sterilus	Taisyklė 5	V	3	31919	08BAL2008	N/A
RR1000	NASATENT	TF45154	Klasė I Sterilus	Taisyklė 5	V	3	12699	06SPAL2009	N/A
					V	3	31919	21BIRŽ2014	N/A

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