ArthroCare Corporation
7000 W William Cannon Dr
Building One
Austin, TX 78735
USA

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Manufacturer's Confirmation in regards to Regulation 2023/607

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

Manufacturer Name	ArthroCare Corporation
Manufacturer Address	7000 W William Cannon Dr Austin, TX 78735
Manufacturer SRN	US-MF-000017581
Notified Body Name	TUV SUD Product Service GmbH
Notified Body Number	0123

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

- The certificates covering devices were valid on the 26 May 2021.
- The devices continue to comply with Directive 93/42/EEC (MDD).
- There are no significant changes in design and intended purpose since 26 May 2021.
- The devices do not present unacceptable risks to health or safety of patients, users or other persons, or other aspects of the protection of public health.
- A quality management system in accordance with Article 10(9), Regulation (EU) 201/745 (MDR) has been put in place by the manufacturer no later than 26 May 2024.
- A formal application to the notified body in accordance with Section 4.3, first subparagraph of Annex VII, Regulation (EU) 2017/745 (MDR) for conformity assessment has been made for the device(s) and a signed written agreement is in place in accordance with Section 4.3. second subparagraph of Annex VII, Regulation 2017/745 (MDR). This was completed prior to the expiry of the relevant certificate(s).
- Post-market surveillance, market surveillance, vigilance, registration of economic operators in accordance with Regulation (EU) 2017/745 (MDR) is in place for the devices listed.

Signature: Date: 14-May-2024 | 20:31:13 BST

d Pena
prove this document
y-2024 | 20:30:53 BST
FA4A7648880EAC17F

Print Name: Pied Title: Senior Regulatory Manager

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Schedule of Devices

Catalog Item	Description	Certificate number	Expiry date on the certificate	Extended expiry date
72290045	WEREWOLF (RF 20000) system	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
72290105	Werewolf Coblation System Controller RF20000 (Sports Medicine	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
72290037	WEREWOLF FLOW 50 Wand	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
72290007	Wired Foot Pedal	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
72290008	Wireless Foot Pedal	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
72290174	WEREWOLF + Power Cord/ Manual – EU English	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
72290172	WEREWOLF + Power Cord/ Manual – W. Europe	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
72290173	WEREWOLF + Power Cord/ Manual – EU Spanish	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
72290177	WEREWOLF + Power Cord/ Manual – Scandinavia	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
72290182	WEREWOLF + Power Cord/ Manual – Switzerland	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
72290146F	WEREWOLF + Controller REFURBISHED	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
72290146S	SVC REPL WEREWOLF + CONTROLLER	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
72290082	ENT WEREWOLF Power Cord/ Manual - W. Europe	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
72290083	ENT WEREWOLF Power Cord/ Manual - EU Spanish	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
72290084	ENT WEREWOLF Power Cord/ Manual UK English	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
72290087	ENT WEREWOLF Power Cord/ Manual - Scandinavia	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
72290144S	WEREWOLF COBLATION System Controller (Sports Medicine and ENT) (Refurbished)	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
72290136	WEREWOLF ENT Adapter	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
72290059	WEREWOLF Power Cord/ Manual- W. Europe	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
72290060	WEREWOLF Power Cord/ Manual- EU Spanish	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
72290061	WEREWOLF Power Cord/ Manual- UK English	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
72290062	WEREWOLF Power Cord/ Manual- Scandinavia	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
72290065	WEREWOLF Power Cord/ Manual-	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028

Catalog Item	Description	Certificate number	Expiry date on the certificate	Extended expiry date
	Switzerland			
72290105S	WEREWOLF COBLATION System Controller (Sports Medicine) (Refurbished)	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
72290038	WEREWOLF FLOW 90 Coblation Wand	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
72290004	Ambient HipVac 50 Wand with Integrated Finger Switches	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
AC2823-01	2.3 mm 35 Degree Short Beve Wand with Integrated Cable	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
AC4050-01	MicroBlator 30 Wand with Integrated Cable	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
AC4330-01	Saber 30 Wand Integrated Cable	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
AC4340-01	CoVator 20 Wand with Integrated Cable	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
AC5531-01	Paragon T2 Wand with Integrated Cable	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
ACH4041-01	Topaz EZ Wand MicroDebrider	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
ACH4045-01	TOPAZ XL Wand IFS	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
ASC1336-01	TurboVac 90 XL Wand with Integrated Cable	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
ASC4250-01	Super TurboVac 90 Wand with Integrated Cable	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
ASC4251-01	StarVac 90 Wand with Integrated Cable	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
ASC4630-01	TriStar 50 Wand with Integrated Cable	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
ASC4730-01	MultiVac 50 XL Wand with Integrated Cable	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
ASC4830-01	Super MultiVac 50 Wand with Integrated Cable	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
ASCA5001-01	Ambient MegaVac 90 Wand	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
ASH4250-01	Super TurboVac Wand with Integrated Finger Switches	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
ASH4830-01	Super TurboVac Wand with Integrated Finger Switches	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
ASHA2530-01	Ambient CoVac 50 Wand with Integrated Finger Switches	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
ASHA3730-01	Ambient CoVac 70 Wand with Integrated Finger Switches	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
ASHA4250-01	Ambient Super TurboVac 90 Wand with Integrated Finger Switches	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
ASHA4830-01	Ambient Super MultiVac 50 Wand with Integrated Finger Switches	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
H4500-00	Quantum 2 (RF 12000) System	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
Q6006-01	Topaz EZ MicroDebrider Wand	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028

Catalog Item	Description	Certificate number	Expiry date on the certificate	Extended expiry date
H3000-01	Foot Control	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
EA8002-00	Flow Control Unit	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
EC8000-01	Coblator II	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
EC8001-01	Coblator II w/out cable 240V	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
EIC5872-01	Evac 70 Xtra Wand	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
EIC5874-01	Evac 70 Xtra HP Wand	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
EIC7070-01	PROcise LW Wand	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
EIC7071-01	PROcise MLW Wand	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
EIC8870-01	ProCISE EZ Wand	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
EIC8872-01	ProCISE XP Wand	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
EIC8875-01	PROcise EZ View Wand	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
EIC8898-01	PROcise Max Wand	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
EICA5872-01	Evac 70 Xtra (MULS) Wand	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
EICA5874-01	Evac 70 Xtra HP (MULS) Wand	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
EICA7070-01	PROcise LW (MULS) Wand	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
EICA7071-01	PROcise MLW (MULS) Wand	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
EICA8870-01	ProCISE EZ (MULS) Wand	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
EICA8872-01	ProCISE XP (MULS) Wand	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
EICA8875-01	PROcise EZ View (MULS) Wand	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
EICA8898-01	PROcise Max (MULS) Wand	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
H3000-03	Shielded Foot Control	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
EIC4835-01	Reflex Ultra PTR Wand with Integrated Cable	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
EIC4845-01	ReFlex Ultra 45 Wand	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
EIC4855-01	ReFlex Ultra 55 Wand	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
EIC4857-01	Reflex Ultra SP Wand	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
EIC6895-01	Turbinator Wand	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
EICA4835-01	Reflex Ultra PTR Wand with Integrated Cable (MULS)	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
EICA4845-01	ReFlex Ultra 45 Wand (MULS)	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
EICA4855-01	ReFlex Ultra 55 Wand (MULS)	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
EICA4857-01	Reflex Ultra SP Wand (MULS)	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
EICA6895-01	Turbinator Wand (MULS)	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
72290134	Coblation Halo Wand	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
72290135	WEREWOLF Irrigation Tube Set	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
72290144	WEREWOLF COBLATION System Controller (Sports Medicine and ENT)	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
72290042	WEREWOLF™ FASTSEAL 6.0 Hemostasis Wand	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
72290146	WEREWOLF+ COBLATION System	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
72290003	Ultrabutton Adjustable Fixation Device	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
OM-8085	SpeedStitch Suture Cartridge (white)	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
OM-8086	SpeedStitch Suture Cartridge (blue	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028

Catalog Item	Description	Certificate number	Expiry date on the certificate	Extended expiry date
	cobraid)			
OM-8087	SpeedStitch Suture Cartridge (black cobraid)	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
OM-8088	SpeedStitch Suture Cartridge (mixed)	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
OM-8175	PerfectPasser Connector MagnumWire (White) Suture Cartridge	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
OM-8176	PerfectPasser Connector MagnumWire (Blue Cobraid) Suture Cartridge	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
OM-8177	PerfectPasser Connector MagnumWire (Black Cobraid) Suture Cartridge	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
OM-8178	PerfectPasser Connector MagnumWire (Mixed Cobraid) Suture Cartridge	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
72290030	Twist Drill For 1.8 Mm Q-Fix Anchor	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
72290031	Twist Drill For 2.8 Mm Q-Fix Anchor	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
72290118	Flexible Drill For 1.8 Mm Q-Fix Suture Anchor	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
72290124	Twist Drill For 1.8 Mm Q-Fix Suture Anchor	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
72290125	Disposable Kit For Qfix 1.8 Mm Mini Suture Anchor	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
72290126	Disposable Kit Xl Qfix 1.8 Mm Mini Suture Anchor	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
25-1810	Disposable Kit For 1.8mm Q-Fix Suture Anchor	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
25-1811	Disposable Kit Xl For 1.8mm Q-Fix Suture Anchor	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
25-2810	Disposable Kit For 2.8mm Q-Fix Suture Anchor	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
23-2009	SpeedLock HIP In-Line Drill, 3.0mm	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
23-2010	SpeedLock HIP 3.0 mm Drill	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
72290128	FIRSTPASS MINI Suture Passer - Straight	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
72290129	FIRSTPASS MINI Suture Passer – Left Curved	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
72290130	FIRSTPASS MINI Suture Passer – Right Curved	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
22-4035	FirstPass Suture Passer	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
22-4036	FirstPass Needle and Suture Capture (5 pk)	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
22-4038	FirstPass ST Suture Passer	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
22-4039	FirstPass ST Suture Passer	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
23-2005	Accu-Pass Direct, Crescent XL	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
OM-7000	SpeedStitch Suturing Device	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028

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Catalog Item	Description	Certificate number	Expiry date on the certificate	Extended expiry date
OM-8000	SmartStitch Suturing Device Handle	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
OM-8010	PerfectPasser Connector Suturing Device	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
OM-8850	SpeedStitch Needle Cassette	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
25-1800	1.8 mm Q-FIX Suture Anchor	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
25-2800	2.8 mm Q-FIX Suture Anchor	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
72290123	QFIX 1.8 MINI Suture Anchor	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
72290001	5.5mm MultiFIX S Ultra	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
72290002	6.5mm MultiFIX S Ultra	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
OM-6500	SpeedScrew 5.5 Implant with Inserter Handle	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
OM-8500	SpeedScrew 6.5 Implant with Inserter Handle	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
23-2001	SpeedLock® HIP Knotless Fixation Implant	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
OM-1502	Magnum2 Knotless Implant	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
RR 1000	NASASTENT	G2S 077112 0041 Rev.00	26-May-2024	31-Dec-2028
RR 600	SINU KNIT DISSOLVABLE DRESSING	G2S 077112 0041 Rev.00	26-May-2024	31-Dec-2028
RR 650	SINU FOAM	G2S 077112 0041 Rev.00	26-May-2024	31-Dec-2028
RR 300	Riemann 3 cm	G2S 077112 0041 Rev.00	26-May-2024	31-Dec-2028
RR 400	Riemann 4 cm	G2S 077112 0041 Rev.00	26-May-2024	31-Dec-2028
RR 450	4.5 cm Anterior	G2S 077112 0041 Rev.00	26-May-2024	31-Dec-2028
RR 500	Goodman 5.5 cm	G2S 077112 0041 Rev.00	26-May-2024	31-Dec-2028
RR 530	Rapid Pac 5.5 Anterior	G2S 077112 0041 Rev.00	26-May-2024	31-Dec-2028
RR 550	5.5 cm Anterior	G2S 077112 0041 Rev.00	26-May-2024	31-Dec-2028
RR 551	5.5 Anterior- Airway	G2S 077112 0041 Rev.00	26-May-2024	31-Dec-2028
RR 750	7.5 cm Anterior/Posterior	G2S 077112 0041 Rev.00	26-May-2024	31-Dec-2028
RR 751	7.5 Ant./Post.-Airway	G2S 077112 0041 Rev.00	26-May-2024	31-Dec-2028
RR 800	Anterior Posterior 8 cm	G2S 077112 0041 Rev.00	26-May-2024	31-Dec-2028
RR 900	Rapid Rhino Nasal Catheter, Posterior	G2S 077112 0041 Rev.00	26-May-2024	31-Dec-2028

DocuSign

Certificate Of Completion

Envelope Id: 573136602A7442DF9085277A371697C0 Status: Completed
Subject: Complete with DocuSign: ARTC Mfr Declaration of Certificate of Validity_Regulation 2023_607_KM ...
Source Envelope:
Document Pages: 6 Signatures: 1 Envelope Originator:
Certificate Pages: 1 Initials: 0 Arnab Sarkar
AutoNav: Enabled TJ Smith & Nephew Limited
EnvelopeId Stamping: Enabled 101 Hessle Road
Time Zone: (UTC) Dublin, Edinburgh, Lisbon, London Hull, Hull HU3 2BN
Arnab.Sarkar@smith-nephew.com
IP Address: 216.222.219.1

Record Tracking

Status: Original Holder: Arnab Sarkar Location: DocuSign
14-May-2024 | 14:19 Arnab.Sarkar@smith-nephew.com

Signer Events	Signature	Timestamp
Piedad Pena Piedad.Pena@smith-nephew.com Senior Manager Regulatory Affairs Smith & Nephew Security Level: Email, Account Authentication (Required)	Signature Adoption: Uploaded Signature Image Signature ID: 5D46F116-173D-4FFF-A4A7-648880EAC17F Using IP Address: 216.222.208.4 With Signing Authentication via DocuSign password With Signing Reasons (on each tab): I approve this document	Sent: 14-May-2024 | 14:21 Viewed: 14-May-2024 | 20:29 Signed: 14-May-2024 | 20:31
Electronic Record and Signature Disclosure: Not Offered via DocuSign		

In Person Signer Events	Signature	Timestamp

Editor Delivery Events	Status	Timestamp

Agent Delivery Events	Status	Timestamp

Intermediary Delivery Events	Status	Timestamp

Certified Delivery Events	Status	Timestamp

Carbon Copy Events	Status	Timestamp

Witness Events	Signature	Timestamp

Notary Events	Signature	Timestamp

Envelope Summary Events	Status	Timestamps
Envelope Sent	Hashed/Encrypted	14-May-2024 | 14:21
Certified Delivered	Security Checked	14-May-2024 | 20:29
Signing Complete	Security Checked	14-May-2024 | 20:31
Completed	Security Checked	14-May-2024 | 20:31

Payment Events	Status	Timestamps

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DECLARATION OF CONFORMITY

Device Name/Device Family Name: Disposable Instruments

Manufacturer's Name & Address: Smith & Nephew, Inc., Endoscopy Division
150 Minuteman Road, Andover, MA 01810

Critical Manufacturing Facilities:
Smith & Nephew, Endoscopy
130 Forbes Boulevard
Mansfield, MA 02048, USA

Smith & Nephew, Orthopedics
1450 E. Brooks Road
Memphis, TN 38116

Dj Orthopedics de Mexico S.A.deC.V.
Carretera Libre Tijuana
Tecate #20230
Parque Industrial EL Florido
Tijuana B.C.
Mexico 22244

ArthroCare Corporation
B32.1, St 2
Zona Franca Coyol
Coyol
Costa Rica

Ceterix Orthopaedics
6500 Kaiser Dr #120
Fremont, CA 94555

Sterilization Sites:
Sterigenics US, LLC
1700 College Blvd
West Memphis, AR 72301

Sterigenics International Inc.
2311 Lincoln Ave,
Hayward, CA 94545

Steris-Isomedix
435 Whitney Street
Northborough, MA 01532

Sterigenics US, LLC
1003 Lakeside Drive
Gurnee, IL 60031

Professional Contract Sterilization (PCS)
40 Myles Standish Boulevard
Taunton, MA 02780

Smith & Nephew, Inc.
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European Authorized Representative: Smith & Nephew Orthopaedics GmbH
Alemannenstraße 14
78532 Tuttlingen
Germany
ec.rep@smith-newphew.com

Relevant Notified Body Number: CE 2797

Notified Body Address: BSi Group The Netherlands B.V.
Say Building, John M. Keynesplein 9
1066 EP Amsterdam
The Netherlands

CE Certificate No.: CE 506114

Product Code(s): See Attached Product List

Technical File Reference Number: 1750065 Rev. BG

Smith & Nephew herein declares under our sole responsibility that the product mentioned within this Declaration of Conformity meet the provisions of the following council directives 93/42/EEC for Medical Devices as amended by 2007/47/EC, II.3 and are entitled to bear the CE mark.

For Class I Devices: 93/42/EEC for Medical Devices as amended by 2007/42/EC, Annex V. This declaration is supported by the self-declaration route to conformance.

All supporting documentation is retained under the premises of the manufacturer.

Michael Secondini

Secondini
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2024 | 14:43:58 BST
95C0164008E5FE81

21-May-2024 | 14:44:01 BST

Printed Name
Regulatory Affairs

Date of Issue

Smith & Nephew, Inc.
Product Technical File

Product List:

Tech File # 1750065 Revision BG

Ref#	Description	Class	Rule	Sterile	Initial date	O* date
4116	ECTRA Procedure Kit	IIa	6	Gamma	4/1997	
4447	Knife, Probe, boxed set of 6	IIa	6	Gamma	4/1997	
4448	Knife, Triangle, boxed set of 6	IIa	6	Gamma	4/1997	
4449	Knife, Retrograde, boxed set of 6	IIa	6	Gamma	4/1997	
010600	Disposable Knife,Hook,3mm (5)	IIa	6	Gamma	11/1998	
010610	Disposable Knife,Rossette,3mm Straight(5)	IIa	6	Gamma	11/1998	
010620	Disposable Knife, Round Tip (Box 5)	IIa	6	Gamma	11/1998	
010630	Disposable Knife, Serrated,(5)	IIa	6	Gamma	11/1998	
010640	Disposable Knife, Serrated Flat (Box 5)	IIa	6	Gamma	11/1998	
010650	Disposable Knife, Sharp Tip	IIa	6	Gamma	11/1998	
010660	Disposable Knife, V Shaped	IIa	6	Gamma	11/1998	
014723	Acufex Smoother Crucial Tool, 7.9	IIa	6	EO	9/2010	
014724	Acufex Smoother Crucial Tool, 9.5	IIa	6	EO	9/2010	
72200819	TwinFix AB Threaded Dilator, 5.0 (new handle)	IIa	6	Gamma	10/2006	
72200820	TwinFix AB Threaded Dilator, 5.0 (new handle)	IIa	6	Gamma	10/2006	
72202621	3.8mm Tapered Awl, Disposable	IIa	6	Gamma	12/2009	
72202674	FAST-FIX 360Knot Pusher/Suture Cutter and Slotted Cannula	IIa	6	EtO	3/2010	
72202675	FAST-FIX 360 Curved Knot Pusher/Suture Cutter and Slotted Cannula	IIa	6	EtO	3/2010	
72202986	3.8mm Straight Awl, Disposable	IIa	6	Gamma	5/2010	
72203951	HEALICOIL REGENESORB 4.75mm Fully Threaded Dilator	IIa	6	Gamma	11/2013	
72203952	HEALICOIL REGENESORB 5.5mm Fully Threaded Dilator	IIa	6	Gamma	11/2013	
72205316	CAP-FIX Blade, Straight	IIa	6	Gamma	2/2020	
72205317	CAP-FIX Blade, Curved	IIa	6	Gamma	2/2020	
CTX-C001	NOVOCUT Suture Manager	IIa	6	Gamma	03/2020	
72205314	CAP-FIX Blade, Straight, with Handle	IIa	6	E-Beam	12/2020	
72205315	CAP-FIX Blade, Curved, with Handle	IIa	6	E-Beam	12/2020	

Obsolete Product List:

Tech File # 1750065 Revision BG

Ref#	Description	Class	Rule	Sterile	Initial date	O* date
010670	O*Disposable Knife Variety Pack	IIa	6	Gamma	11/1998	12/1998
012608	O*Meniscal Stitching Needles 10" (Box 6)	IIa	6	N/A	3/1997	12/2012
3134114	O* SOD, Disposable Knife Hook	IIa	6	N/A	5/1999	11/2009
3134149	O*SOD, Trailblazer, 2.0mm Cannulated	IIa	6	N/A	5/1999	11/2009
6900341	O* SOD, Spinal Needle, 17 gage	IIa	6	N/A	3/2000	9/2001
7207654	O*Awl, Rotorloc	IIa	6	Gamma	3/2000	8/2003
7209084	O* Knot Pusher /Suture Cutter	IIa	6	EO	4/2001	11/2010
7210076	O* FasT-Fix Curved Knot Pusher/Suture cutter	IIa	6	EO	3/2004	11/2010
7209417	O*Quick-T Knot Pusher Suture Cutter	IIa	6	EO	10/2004	05/2016
7210383	O*TwinFix AB 6.5 Threaded Dialator	IIa	6	Gamma	10/2003	08/2016
7209298	O*TwinFix AB 5.0 Dialator	IIa	6	Gamma	6/2002	08/2016
7210693	O*(5) Suture Shuttle Needle	IIa	6	Gamma	6/2004	10/2016

Smith & Nephew, Inc.
Product Technical File

Obsolete Product List:

Tech File # 1750065 Revision BG

72200721	O* (10) Accu-Pass Suture Shuttle, Monofilament #0	IIa	6	Gamma	8/2006	5/2009
72200937	O*TruKor Drill Sleeve 5mm, Green	IIa	6	Gamma	8/2005	01/2014
72200938	O*TruKor Drill Sleeve 7mm, Red	IIa	6	Gamma	8/2005	01/2014
72200939	O*TruKor Drill Sleeve 9mm, Blue	IIa	6	Gamma	8/2005	01/2014
72200940	O*TruKor Drill Sleeve 11mm, Purple	IIa	6	Gamma	8/2005	01/2014
72203307	O*BEAVER BLADE	IIa	6	EtO	11/2011	06/2016
013583	O*Isotac (box of 6)	IIa	6	Gamma	3/1997	01/2021
72202545	Graft Sizing Block 6mm - 12mm	IIa	6	EtO	1/2010	06/2021
72201899	O*FOOTPRINT Tension Tuner	IIa	6	Gamma	9/2008	05/2022
72203874	O*HEALICORE Inserts and Transfer Tube 9-10mm; *(2) Inserts 9-10mm, (1) Transfer Tube 9-10mm*	IIa	6	Gamma	4/2015	10/2020
72203875	O*HEALICORE Inserts and Transfer Tube 7-8mm; *(2) Inserts 7-8mm, (1) Transfer Tube 7-8mm*	IIa	6	Gamma	4/2015	10/2020
72203876	O*HEALICORE Inserts and Transfer Tube 6mm; *(2) Inserts 6mm, (1) Transfer Tube 6mm*	IIa	6	Gamma	4/2015	10/2020
7210450	O* (10)Suture Funnel	I Sterile	1	Gamma	4/2004	05/2023
7207690	O* Trigger Finger Retrograde Knife (pkg of 6)	IIa	6	Gamma	11/2000	05/2024
7207693	O* Trigger Finger Triangle Knife (pkg of 6)	IIa	6	Gamma	11/2000	05/2024

MDR Product List

Ref#	Description	Class	Rule	Sterile	Initial Date	MDR Date	MDR Technical Documentation File
7209950	(10) Suture Threader	1 Sterile	1	Gamma	1/2003	9/2023	ENDO-TF-025
013593	(6) Suture Retriever	IIA	6	Gamma	10/1997	1/2024	ENDO-TF-026
014617	(4) TRANSPORTER Suture Retriever	IIA	6	Gamma	10/1997	1/2024	ENDO-TF-026
7209485	(1) Outside-In Meniscal Repair System Meniscus Mender II	IIA	6	Gamma	7/2002	1/2024	ENDO-TF-026
7210423	(1) ACCU-PASS Suture Shuttle, Left 45° Curve	IIA	6	Gamma	9/2005	1/2024	ENDO-TF-026
7210424	(1) ACCU-PASS Suture Shuttle, Right 45° Curve	IIA	6	Gamma	9/2005	1/2024	ENDO-TF-026
7210425	(1) ACCU-PASS Suture Shuttle, 45° Up	IIA	6	Gamma	5/2005	1/2024	ENDO-TF-026
7210426	(1) ACCU-PASS Suture Shuttle, Straight	IIA	6	Gamma	5/2005	1/2024	ENDO-TF-026
7210427	(1) ACCU-PASS Suture Shuttle, Crescent	IIA	6	Gamma	5/2005	1/2024	ENDO-TF-026
7210752	TFCC Mender, Disposable Suture System	IIA	6	Gamma	9/2004	1/2024	ENDO-TF-026
72200418	(1) ACCU-PASS Suture Shuttle, Big Curve	IIA	6	Gamma	10/2005	1/2024	ENDO-TF-026
72200419	(1) ACCU-PASSs Suture Shuttle 70° Upbend	IIA	6	Gamma	9/2005	1/2024	ENDO-TF-026
72201076	(1) ACCU-PASS Suture Shuttle, J-Hook	IIA	6	Gamma	11/2007	1/2024	ENDO-TF-026

Smith & Nephew, Inc.
Product Technical File

72201361	(10) ACCU-PASS Suture Shuttle Monofilament #1	IIA	6	Gamma	3/2007	1/2024	ENDO-TF-026
72201406	(1) Suture Passer, 12"	IIA	6	Gamma	2/2007	1/2024	ENDO-TF-026
72201407	(1) Suture Passer, 2"	IIA	6	Gamma	2/2007	1/2024	ENDO-TF-026
72201537	(1) ULTRA FAST-FIX Meniscal Knot Pusher and Suture Cutter	IIA	6	EtO	11/2007	1/2024	ENDO-TF-026
72202868	(1) Needle for Meniscal Stitcher, 0.033 x 10"	IIA	6	Gamma	4/2012	1/2024	ENDO-TF-026
72203793	(5) TRUEPASS Disposable Needles	IIA	6	Gamma	12/2013	1/2024	ENDO-TF-026
71934994	Loop Tip Guidewire	IIA	6	Gamma	5/2014	1/2024	ENDO-TF-026

These SKUs have transitioned their EU compliance from Medical Device Directive 93/42/EEC (MDD) to Medical Device Regulation (EU) 2017/745 (MDR). Going forward, tracking and maintenance of device conformance will be captured in corresponding MDR Technical Documentation. Devices manufactured and placed on the market prior to this transition still maintain compliance to the MDD. Reference the GSPR checklist within the corresponding MDR Technical Documentation File for details on compliance to MDD Essential Requirements.

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Completed	Security Checked	21-May-2024 | 14:44

Payment Events	Status	Timestamps

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SmithNephew

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Memphis, TN 38116

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ArthroCare korporacija
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1066 EP Amsterdamas

Olandija

CE sertifikato numeris.: CE 506114

Produkto kodas (-ai): žr. pridedamą produktų sąrašą.

Techninės bylos nuorodos numeris: 1750065 Rev. BG

„Smith & Nephew“, prisiimdama savo atsakomybę, pareiškia, kad šioje atitikties deklaracijoje nurodytas gaminys atitinka toliau pateiktų Tarybos direktyvų 93/42/EEB dėl medicinos prietaisų su pakeitimais, padarytais 2007/47/EB, II.3 nuostatas ir turi teisę turėti CE ženklą. I klasės prietaisams: 93/42/EEB dėl medicinos prietaisų su pakeitimais, padarytais 2007/42/EB, V priedas. deklaraciją patvirtina savideklaravimo būdas. Visi patvirtinamieji dokumentai saugomi gamintojo patalpose.

Michael Secondini

Michael Secondini
I approve this document
21-May-2024 | 14:43:58 BST
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21-May-2024 | 14:44:01 BST

Atspausdintas vardas | Parašas | Išleidimo data

Reguliuotojo dalykas

Smith & Nephew, Inc.
Gaminio techninė byla

Produktų sąrašas:

Techninis failas # 1750065 BG peržiūra

Ref#	Description	Class	Rule	Sterile	Initial date	O* date
4116	ECTRA Procedure Kit	IIa	6	Gamma	4/1997	
4447	Knife, Probe, boxed set of 6	IIa	6	Gamma	4/1997	
4448	Knife, Triangle, boxed set of 6	IIa	6	Gamma	4/1997	
4449	Knife, Retrograde, boxed set of 6	IIa	6	Gamma	4/1997	
010600	Disposable Knife,Hook,3mm (5)	IIa	6	Gamma	11/1998	
010610	Disposable Knife,Rossette,3mm Straight(5)	IIa	6	Gamma	11/1998	
010620	Disposable Knife, Round Tip (Box 5)	IIa	6	Gamma	11/1998	
010630	Disposable Knife, Serrated,(5)	IIa	6	Gamma	11/1998	
010640	Disposable Knife, Serrated Flat (Box 5)	IIa	6	Gamma	11/1998	
010650	Disposable Knife, Sharp Tip	IIa	6	Gamma	11/1998	
010660	Disposable Knife, V Shaped	IIa	6	Gamma	11/1998	
014723	Acufex Smoother Crucial Tool, 7.9	IIa	6	EO	9/2010	
014724	Acufex Smoother Crucial Tool, 9.5	IIa	6	EO	9/2010	
72200819	TwinFix AB Threaded Dilator, 5.0 (new handle)	IIa	6	Gamma	10/2006	
72200820	TwinFix AB Threaded Dilator, 5.0 (new handle)	IIa	6	Gamma	10/2006	
72202621	3.8mm Tapered Awl, Disposable	IIa	6	Gamma	12/2009	
72202674	FAST-FIX 360Knot Pusher/Suture Cutter and Slotted Cannula	IIa	6	EtO	3/2010	
72202675	FAST-FIX 360 Curved Knot Pusher/Suture Cutter and Slotted Cannula	IIa	6	EtO	3/2010	
72202986	3.8mm Straight Awl, Disposable	IIa	6	Gamma	5/2010	
72203951	HEALICOIL REGENESORB 4.75mm Fully Threaded Dilator	IIa	6	Gamma	11/2013	
72203952	HEALICOIL REGENESORB 5.5mm Fully Threaded Dilator	IIa	6	Gamma	11/2013	
72205316	CAP-FIX Blade, Straight	IIa	6	Gamma	2/2020	
72205317	CAP-FIX Blade, Curved	IIa	6	Gamma	2/2020	
CTX-C001	NOVOCUT Suture Manager	IIa	6	Gamma	03/2020	
72205314	CAP-FIX Blade, Straight, with Handle	IIa	6	E-Beam	12/2020	
72205315	CAP-FIX Blade, Curved, with Handle	IIa	6	E-Beam	12/2020	

Senos kartos produktų sąrašas:

Techninis failas # 1750065 BG peržiūra

Ref#	Description	Class	Rule	Sterile	Initial date	O* date
010670	O*Disposable Knife Variety Pack	IIa	6	Gamma	11/1998	12/1998
012608	O*Meniscal Stitching Needles 10" (Box 6)	IIa	6	N/A	3/1997	12/2012
3134114	O* SOD, Disposable Knife Hook	IIa	6	N/A	5/1999	11/2009
3134149	O*SOD, Trailblazer, 2.0mm Cannulated	IIa	6	N/A	5/1999	11/2009
6900341	O* SOD, Spinal Needle, 17 gage	IIa	6	N/A	3/2000	9/2001
7207654	O*Awl, Rotorloc	IIa	6	Gamma	3/2000	8/2003
7209084	O* Knot Pusher /Suture Cutter	IIa	6	EO	4/2001	11/2010
7210076	O* FasT-Fix Curved Knot Pusher/Suture cutter	IIa	6	EO	3/2004	11/2010
7209417	O*Quick-T Knot Pusher Suture Cutter	IIa	6	EO	10/2004	05/2016
7210383	O*TwinFix AB 6.5 Threaded Dialator	IIa	6	Gamma	10/2003	08/2016
7209298	O*TwinFix AB 5.0 Dialator	IIa	6	Gamma	6/2002	08/2016
7210693	O*(5) Suture Shuttle Needle	IIa	6	Gamma	6/2004	10/2016

Senos kartos produktų sąrašas:

Techninis failas # 1750065 BG peržiūra

72200721	O* (10) Accu-Pass Suture Shuttle, Monofilament #0	IIa	6	Gamma	8/2006	5/2009
72200937	O*TruKor Drill Sleeve 5mm, Green	IIa	6	Gamma	8/2005	01/2014
72200938	O*TruKor Drill Sleeve 7mm, Red	IIa	6	Gamma	8/2005	01/2014
72200939	O*TruKor Drill Sleeve 9mm, Blue	IIa	6	Gamma	8/2005	01/2014
72200940	O*TruKor Drill Sleeve 11mm, Purple	IIa	6	Gamma	8/2005	01/2014
72203307	O*BEAVER BLADE	IIa	6	EtO	11/2011	06/2016
013583	O*Isotac (box of 6)	IIa	6	Gamma	3/1997	01/2021
72202545	Graft Sizing Block 6mm - 12mm	IIa	6	EtO	1/2010	06/2021
72201899	O*FOOTPRINT Tension Tuner	IIa	6	Gamma	9/2008	05/2022
72203874	O*HEALICORE Inserts and Transfer Tube 9-10mm; *(2) Inserts 9-10mm, (1) Transfer Tube 9-10mm*	IIa	6	Gamma	4/2015	10/2020
72203875	O*HEALICORE Inserts and Transfer Tube 7-8mm; *(2) Inserts 7-8mm, (1) Transfer Tube 7-8mm*	IIa	6	Gamma	4/2015	10/2020
72203876	O*HEALICORE Inserts and Transfer Tube 6mm; *(2) Inserts 6mm, (1) Transfer Tube 6mm*	IIa	6	Gamma	4/2015	10/2020
7210450	O* (10)Suture Funnel	I Sterile	1	Gamma	4/2004	05/2023
7207690	O* Trigger Finger Retrograde Knife (pkg of 6)	IIa	6	Gamma	11/2000	05/2024
7207693	O* Trigger Finger Triangle Knife (pkg of 6)	IIa	6	Gamma	11/2000	05/2024

MDR produktų sąrašas:

Ref#	Description	Class	Rule	Sterile	Initial Date	MDR Date	MDR Technical Documentation File
7209950	(10) Suture Threader	I Sterile	1	Gamma	1/2003	9/2023	ENDO-TF-025
013593	(6) Suture Retriever	IIA	6	Gamma	10/1997	1/2024	ENDO-TF-026
014617	(4) TRANSPORTER Suture Retriever	IIA	6	Gamma	10/1997	1/2024	ENDO-TF-026
7209485	(1) Outside-In Meniscal Repair System Meniscus Mender II	IIA	6	Gamma	7/2002	1/2024	ENDO-TF-026
7210423	(1) ACCU-PASS Suture Shuttle, Left 45° Curve	IIA	6	Gamma	9/2005	1/2024	ENDO-TF-026
7210424	(1) ACCU-PASS Suture Shuttle, Right 45° Curve	IIA	6	Gamma	9/2005	1/2024	ENDO-TF-026
7210425	(1) ACCU-PASS Suture Shuttle, 45° Up	IIA	6	Gamma	5/2005	1/2024	ENDO-TF-026
7210426	(1) ACCU-PASS Suture Shuttle, Straight	IIA	6	Gamma	5/2005	1/2024	ENDO-TF-026
7210427	(1) ACCU-PASS Suture Shuttle, Crescent	IIA	6	Gamma	5/2005	1/2024	ENDO-TF-026
7210752	TFCC Mender, Disposable Suture System	IIA	6	Gamma	9/2004	1/2024	ENDO-TF-026
72200418	(1) ACCU-PASS Suture Shuttle, Big Curve	IIA	6	Gamma	10/2005	1/2024	ENDO-TF-026
72200419	(1) ACCU-PASSs Suture Shuttle 70° Upbend	IIA	6	Gamma	9/2005	1/2024	ENDO-TF-026
72201076	(1) ACCU-PASS Suture Shuttle, J-Hook	IIA	6	Gamma	11/2007	1/2024	ENDO-TF-026

Smith & Nephew, Inc. Produktų techniniai failai:

72201361	(10) ACCU-PASS Suture Shuttle Monofilament #1	IIA	6	Gamma	3/2007	1/2024	ENDO-TF-026
72201406	(1) Suture Passer, 12"	IIA	6	Gamma	2/2007	1/2024	ENDO-TF-026
72201407	(1) Suture Passer, 2"	IIA	6	Gamma	2/2007	1/2024	ENDO-TF-026
72201537	(1) ULTRA FAST-FIX Meniscal Knot Pusher and Suture Cutter	IIA	6	EtO	11/2007	1/2024	ENDO-TF-026
72202868	(1) Needle for Meniscal Stitcher, 0.033 x 10"	IIA	6	Gamma	4/2012	1/2024	ENDO-TF-026
72203793	(5) TRUEPASS Disposable Needles	IIA	6	Gamma	12/2013	1/2024	ENDO-TF-026
71934994	Loop Tip Guidewire	IIA	6	Gamma	5/2014	1/2024	ENDO-TF-026

Šie SKU perkėlė ES atitiktį iš Medicinos prietaisų direktyvos 93/42/EEB (MDD) į medicinos prietaisų reglamentą (ES) 2017/745 (MDR). Toliau įrenginio atitikties stebėjimas ir priežiūra bus užfiksuoti atitinkamame MDR. Techninė dokumentacija. Prietaisai, pagaminti ir pateikti į rinką iki šio perėjimo, vis dar atitinka MDD. Norėdami gauti daugiau informacijos apie atitiktį MDD Essential, žr. GSPR kontrolinį sąrašą atitinkamame MDR techninės dokumentacijos faile. Reikalavimai.

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Michael Secondini Michael.Secondini@smith-nephew.com Sr. Manager, Regulatory Affairs Smith & Nephew Security Level: Email, Account Authentication (Required), Login with SSO	Signature Adoption: Pre-selected Style Signature ID: 84734DD7-36D0-45C9-95C0-164008E5FE81 Using IP Address: 216.222.208.4 With Signing Authentication via DocuSign password With Signing Reasons (on each tab): I approve this document	Sent: 14-May-2024 | 20:19 Viewed: 21-May-2024 | 14:42 Signed: 21-May-2024 | 14:44

Electronic Record and Signature Disclosure:
Not Offered via DocuSign

In Person Signer Events	Signature	Timestamp

Editor Delivery Events	Status	Timestamp

Agent Delivery Events	Status	Timestamp

Intermediary Delivery Events	Status	Timestamp

Certified Delivery Events	Status	Timestamp

Carbon Copy Events	Status	Timestamp

Witness Events	Signature	Timestamp

Notary Events	Signature	Timestamp

Envelope Summary Events	Status	Timestamps
Envelope Sent	Hashed/Encrypted	14-May-2024 | 20:19
Certified Delivered	Security Checked	21-May-2024 | 14:42
Signing Complete	Security Checked	21-May-2024 | 14:44
Completed	Security Checked	21-May-2024 | 14:44

Payment Events	Status	Timestamps

ArthroCare Corporation
7000 W William Cannon Dr
Building One
Austin, TX 78735
USA

T:+ 1 512-391-3900
www.smith-nephew.com

SmithNephew

Gamintojo patvirtinimas dėl Reglamento 2023/607

Dėl sertifikatų, išduotų pagal Tarybos direktyvą 93/42/EEB dėl medicinos prietaisų (MDD), (direktyviniai pažymėjimai) ir jų galiojimas pagal Reglamento (ES) 2017/745 dėl medicinos 120 straipsnio 2 dalį. Prietaisai su pakeitimais, padarytais 2023 m. kovo 20 d. Reglamentu 2023/607 (MDR) ir įrenginių ir jo gamintojo atitiktį tolesnio jų pateikimo sąlygoms pagal MDR 120 straipsnio 3 dalį.

Gamintojo pavadinimas	ArthroCare Corporation
Gamintojo adresas	7000 W William Cannon Dr Austin, TX 78735
Gamintojo SRN	US-MF-000017581
Informuotos įstaigos pavadinimas	TUV SUD Product Service GmbH
Informuotos įstaigos numeris	0123

Tai patvirtinimas, kad įrenginiai, kuriems taikomi toliau išvardyti sertifikatai, atitinka toliau nurodytus reikalavimus sertifikatų, išduotų pagal Tarybos direktyvą 93/42/EEB, pratęsimo sąlygos
dėl medicinos prietaisų (MDD), kaip nurodyta Reglamente (ES) 2023/607, iš dalies keičiančiame Reglamentą (ES) 2017/745
medicinos prietaisuose:

- Įrenginiams taikomi sertifikatai galiojo 2021 m. gegužės 26 d.
- Prietaisai ir toliau atitinka Direktyvą 93/42/EEB (MDD).
- Nuo 2021 m. gegužės 26 d. esminių dizaino ir paskirties pakeitimų nėra.
- Prietaisai nekelia nepriimtino pavojaus pacientų, naudotojų ar kitų asmenų sveikatai ar saugai
asmenų ar kitais visuomenės sveikatos apsaugos aspektais.
- Kokybės valdymo sistema pagal Reglamento (ES) 201/745 10 straipsnio 9 dalį.
(MDR) gamintojas įdiegė ne vėliau kaip 2024 m. gegužės 26 d.
- Oficiali paraiška notifikuotajai įstaigai pagal 4.3 skirsnio pirmą pastraipą
VII priedas, Reglamentas (ES) 2017/745 (MDR) dėl atitikties vertinimo buvo atliktas
prietaisas (-ai) ir yra pasirašyta rašytinė sutartis pagal 4.3 skirsnį. antra
2017/745 (MDR) VII priedo pastraipą. Tai buvo baigta prieš
atitinkamo (-ų) sertifikato (-ų) galiojimo laikas.
- Priežiūra po pateikimo rinkai, rinkos priežiūra, budrumas, ūkio subjektų registravimas
išvardytiems prietaisams taikoma pagal Reglamentą (ES) 2017/745 (MDR).

Produktų sąrašas:

Catalog Item	Description	Certificate number	Expiry date on the certificate	Extended expiry date
72290045	WEREWOLF (RF 20000) system	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
72290105	Werewolf Coblation System Controller RF20000 (Sports Medicine	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
72290037	WEREWOLF FLOW 50 Wand	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
72290007	Wired Foot Pedal	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
72290008	Wireless Foot Pedal	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
72290174	WEREWOLF + Power Cord/ Manual – EU English	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
72290172	WEREWOLF + Power Cord/ Manual – W. Europe	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
72290173	WEREWOLF + Power Cord/ Manual – EU Spanish	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
72290177	WEREWOLF + Power Cord/ Manual – Scandinavia	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
72290182	WEREWOLF + Power Cord/ Manual – Switzerland	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
72290146F	WEREWOLF + Controller REFURBISHED	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
72290146S	SVC REPL WEREWOLF + CONTROLLER	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
72290082	ENT WEREWOLF Power Cord/ Manual - W. Europe	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
72290083	ENT WEREWOLF Power Cord/ Manual - EU Spanish	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
72290084	ENT WEREWOLF Power Cord/ Manual UK English	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
72290087	ENT WEREWOLF Power Cord/ Manual - Scandinavia	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
72290144S	WEREWOLF COBLATION System Controller (Sports Medicine and ENT) (Refurbished)	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
72290136	WEREWOLF ENT Adapter	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
72290059	WEREWOLF Power Cord/ Manual- W. Europe	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
72290060	WEREWOLF Power Cord/ Manual- EU Spanish	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
72290061	WEREWOLF Power Cord/ Manual- UK English	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
72290062	WEREWOLF Power Cord/ Manual- Scandinavia	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
72290065	WEREWOLF Power Cord/ Manual-	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028

Catalog Item	Description	Certificate number	Expiry date on the certificate	Extended expiry date
H3000-01	Foot Control	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
EA8002-00	Flow Control Unit	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
EC8000-01	Coblator II	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
EC8001-01	Coblator II w/out cable 240V	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
EIC5872-01	Evac 70 Xtra Wand	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
EIC5874-01	Evac 70 Xtra HP Wand	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
EIC7070-01	PROcise LW Wand	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
EIC7071-01	PROcise MLW Wand	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
EIC8870-01	ProCISE EZ Wand	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
EIC8872-01	ProCISE XP Wand	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
EIC8875-01	PROcise EZ View Wand	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
EIC8898-01	PROcise Max Wand	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
EICAS872-01	Evac 70 Xtra (MULS) Wand	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
EICAS874-01	Evac 70 Xtra HP (MULS) Wand	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
EICA7070-01	PROcise LW (MULS) Wand	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
EICA7071-01	PROcise MLW (MULS) Wand	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
EICA8870-01	ProCISE EZ (MULS) Wand	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
EICA8872-01	ProCISE XP (MULS) Wand	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
EICA8875-01	PROcise EZ View (MULS) Wand	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
EICA8898-01	PROcise Max (MULS) Wand	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
H3000-03	Shielded Foot Control	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
EIC4835-01	Reflex Ultra PTR Wand with Integrated Cable	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
EIC4845-01	ReFlex Ultra 45 Wand	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
EIC4855-01	ReFlex Ultra 55 Wand	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
EIC4857-01	Reflex Ultra SP Wand	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
EIC6895-01	Turbinator Wand	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
EICA4835-01	Reflex Ultra PTR Wand with Integrated Cable (MULS)	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
EICA4845-01	ReFlex Ultra 45 Wand (MULS)	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
EICA4855-01	ReFlex Ultra 55 Wand (MULS)	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
EICA4857-01	Reflex Ultra SP Wand (MULS)	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
EICA6895-01	Turbinator Wand (MULS)	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
72290134	Coblation Halo Wand	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
72290135	WEREWOLF Irrigation Tube Set	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
72290144	WEREWOLF COBLATION System Controller (Sports Medicine and ENT)	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
72290042	WEREWOLF™ FASTSEAL 6.0 Hemostasis Wand	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
72290146	WEREWOLF+ COBLATION System	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
72290003	Ultrabutton Adjustable Fixation Device	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
OM-8085	SpeedStitch Suture Cartridge (white)	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
OM-8086	SpeedStitch Suture Cartridge (blue	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028

Catalog Item	Description	Certificate number	Expiry date on the certificate	Extended expiry date
	Switzerland			
72290105S	WEREWOLF COBLATION System Controller (Sports Medicine) (Refurbished)	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
72290038	WEREWOLF FLOW 90 Coblation Wand	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
72290004	Ambient HipVac 50 Wand with Integrated Finger Switches	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
AC2823-01	2.3 mm 35 Degree Short Beve Wand with Integrated Cable	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
AC4050-01	MicroBlator 30 Wand with Integrated Cable	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
AC4330-01	Saber 30 Wand Integrated Cable	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
AC4340-01	CoVator 20 Wand with Integrated Cable	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
AC5531-01	Paragon T2 Wand with Integrated Cable	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
ACH4041-01	Topaz EZ Wand MicroDebrider	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
ACH4045-01	TOPAZ XL Wand IFS	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
ASC1336-01	TurboVac 90 XL Wand with Integrated Cable	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
ASC4250-01	Super TurboVac 90 Wand with Integrated Cable	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
ASC4251-01	StarVac 90 Wand with Integrated Cable	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
ASC4630-01	TriStar 50 Wand with Integrated Cable	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
ASC4730-01	MultiVac 50 XL Wand with Integrated Cable	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
ASC4830-01	Super MultiVac 50 Wand with Integrated Cable	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
ASCAS001-01	Ambient MegaVac 90 Wand	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
ASH4250-01	Super TurboVac Wand with Integrated Finger Switches	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
ASH4830-01	Super TurboVac Wand with Integrated Finger Switches	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
ASHA2530-01	Ambient CoVac 50 Wand with Integrated Finger Switches	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
ASHA3730-01	Ambient CoVac 70 Wand with Integrated Finger Switches	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
ASHA4250-01	Ambient Super TurboVac 90 Wand with Integrated Finger Switches	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
ASHA4830-01	Ambient Super MultiVac 50 Wand with Integrated Finger Switches	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
H4500-00	Quantum 2 (RF 12000) System	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
Q6006-01	Topaz EZ MicroDebrider Wand	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028

Catalog Item	Description	Certificate number	Expiry date on the certificate	Extended expiry date
	cobraid)			
OM-8087	SpeedStitch Suture Cartridge (black cobraid)	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
OM-8088	SpeedStitch Suture Cartridge (mixed)	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
OM-8175	PerfectPasser Connector MagnumWire (White) Suture Cartridge	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
OM-8176	PerfectPasser Connector MagnumWire (Blue Cobraid) Suture Cartridge	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
OM-8177	PerfectPasser Connector MagnumWire (Black Cobraid) Suture Cartridge	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
OM-8178	PerfectPasser Connector MagnumWire (Mixed Cobraid) Suture Cartridge	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
72290030	Twist Drill For 1.8 Mm Q-Fix Anchor	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
72290031	Twist Drill For 2.8 Mm Q-Fix Anchor	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
72290118	Flexible Drill For 1.8 Mm Q-Fix Suture Anchor	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
72290124	Twist Drill For 1.8 Mm Q-Fix Suture Anchor	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
72290125	Disposable Kit For Qfix 1.8 Mm Mini Suture Anchor	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
72290126	Disposable Kit Xl Qfix 1.8 Mm Mini Suture Anchor	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
25-1810	Disposable Kit For 1.8mm Q-Fix Suture Anchor	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
25-1811	Disposable Kit Xl For 1.8mm Q-Fix Suture Anchor	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
25-2810	Disposable Kit For 2.8mm Q-Fix Suture Anchor	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
23-2009	SpeedLock HIP In-Line Drill, 3.0mm	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
23-2010	SpeedLock HIP 3.0 mm Drill	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
72290128	FIRSTPASS MINI Suture Passer - Straight	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
72290129	FIRSTPASS MINI Suture Passer – Left Curved	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
72290130	FIRSTPASS MINI Suture Passer – Right Curved	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
22-4035	FirstPass Suture Passer	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
22-4036	FirstPass Needle and Suture Capture (5 pk)	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
22-4038	FirstPass ST Suture Passer	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
22-4039	FirstPass ST Suture Passer	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
23-2005	Accu-Pass Direct, Crescent XL	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
OM-7000	SpeedStitch Suturing Device	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028

Catalog Item	Description	Certificate number	Expiry date on the certificate	Extended expiry date
OM-8000	SmartStitch Suturing Device Handle	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
OM-8010	PerfectPasser Connector Suturing Device	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
OM-8850	SpeedStitch Needle Cassette	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
25-1800	1.8 mm Q-FIX Suture Anchor	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
25-2800	2.8 mm Q-FIX Suture Anchor	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
72290123	QFIX 1.8 MINI Suture Anchor	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
72290001	5.5mm MultiFIX S Ultra	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
72290002	6.5mm MultiFIX S Ultra	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
OM-6500	SpeedScrew 5.5 Implant with Inserter Handle	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
OM-8500	SpeedScrew 6.5 Implant with Inserter Handle	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
23-2001	SpeedLock® HIP Knotless Fixation Implant	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
OM-1502	Magnum2 Knotless Implant	G1 077112 0040 Rev. 00	26-May-2024	31-Dec-2028
RR 1000	NASASTENT	G2S 077112 0041 Rev.00	26-May-2024	31-Dec-2028
RR 600	SINU KNIT DISSOLVABLE DRESSING	G2S 077112 0041 Rev.00	26-May-2024	31-Dec-2028
RR 650	SINU FOAM	G2S 077112 0041 Rev.00	26-May-2024	31-Dec-2028
RR 300	Riemann 3 cm	G2S 077112 0041 Rev.00	26-May-2024	31-Dec-2028
RR 400	Riemann 4 cm	G2S 077112 0041 Rev.00	26-May-2024	31-Dec-2028
RR 450	4.5 cm Anterior	G2S 077112 0041 Rev.00	26-May-2024	31-Dec-2028
RR 500	Goodman 5.5 cm	G2S 077112 0041 Rev.00	26-May-2024	31-Dec-2028
RR 530	Rapid Pac 5.5 Anterior	G2S 077112 0041 Rev.00	26-May-2024	31-Dec-2028
RR 550	5.5 cm Anterior	G2S 077112 0041 Rev.00	26-May-2024	31-Dec-2028
RR 551	5.5 Anterior- Airway	G2S 077112 0041 Rev.00	26-May-2024	31-Dec-2028
RR 750	7.5 cm Anterior/Posterior	G2S 077112 0041 Rev.00	26-May-2024	31-Dec-2028
RR 751	7.5 Ant./Post.-Airway	G2S 077112 0041 Rev.00	26-May-2024	31-Dec-2028
RR 800	Anterior Posterior 8 cm	G2S 077112 0041 Rev.00	26-May-2024	31-Dec-2028
RR 900	Rapid Rhino Nasal Catheter, Posterior	G2S 077112 0041 Rev.00	26-May-2024	31-Dec-2028

DocuSign

Certificate Of Completion

Envelope Id: 573136602A7442DF9085277A371697C0 Status: Completed

Subject: Complete with DocuSign: ARTC Mfr Declaration of Certificate of Validity_Regulation 2023_607_KM ...

Source Envelope:

Document Pages: 6 Signatures: 1 Envelope Originator:

Certificate Pages: 1 Initials: 0 Arnab Sarkar

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EnvelopeId Stamping: Enabled 101 Hessle Road

Time Zone: (UTC) Dublin, Edinburgh, Lisbon, London Hull, Hull HU3 2BN

Arnab.Sarkar@smith-nephew.com

IP Address: 216.222.219.1

Record Tracking

Status: Original Holder: Arnab Sarkar Location: DocuSign

14-May-2024 | 14:19 Arnab.Sarkar@smith-nephew.com

Signer Events	Signature	Timestamp
Piedad Pena		Sent: 14-May-2024 | 14:21
Piedad.Pena@smith-nephew.com		Viewed: 14-May-2024 | 20:29
Senior Manager Regulatory Affairs		Signed: 14-May-2024 | 20:31
Smith & Nephew		
Security Level: Email, Account Authentication (Required)	Signature Adoption: Uploaded Signature Image Signature ID: 5D46F116-173D-4FFF-A4A7-648880EAC17F Using IP Address: 216.222.208.4	
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In Person Signer Events	Signature	Timestamp

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Agent Delivery Events	Status	Timestamp

Intermediary Delivery Events	Status	Timestamp

Certified Delivery Events	Status	Timestamp

Carbon Copy Events	Status	Timestamp

Witness Events	Signature	Timestamp

Notary Events	Signature	Timestamp

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Signing Complete	Security Checked	14-May-2024 | 20:31
Completed	Security Checked	14-May-2024 | 20:31

Payment Events	Status	Timestamps

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سميث و نفيو م م ح
ص. ب رقم ٩٧١٥
دبي - ا.ع.م.

ص. ب رقم ١٦٩٩٣
جبل علي ، دبي - ا.ع.م.

هاتف ٩١١١ ٤٢٩ ٤ ٩٧١+
فاكس ٩١٠٠ ٤٢٩ ٤ ٩٧١+

UAB Osteca

28.03.2025

Authorization Letter

Basel AbouJalala, as authorized signatory for and on behalf of Smith & Nephew FZE, having its principal place of business at 1st Floor, Building 52, Dubai Healthcare City, PO Box 9715, Dubai, UAE (**S+N**), hereby confirms that UAB Osteca having its registered office Danes str. 47 LT-92108 Klaipeda, Lithuania,(the **Distributor**) is authorized to act as distributor of the S+N products listed in Schedule 1 (the **Products**) in Lithuania (the **Territory**), pursuant to the terms of a territory sales agreement between S+N and Distributor with an initial effective date of 01.01.2017 (the **TSA**). We further confirm that the TSA is currently in force 31.03.2026. In the event of termination or expiry of the TSA for whatever reason, this letter shall also automatically cease to have effect.

Yours faithfully,

Signed for and on behalf of Smith & Nephew FZE.

Name: Basel AbouJalala
Title: SVP & General Manager Emerging M
Date:

PM PDT

Schedule 1

List of Products the Distributor is authorized to register, import and sell:

1. Smith & Nephew Advanced Wound Management Products
2. Smith & Nephew Endoscopy / Sports Medicine Products
3. Smith & Nephew Orthopaedic Trauma Products
4. Smith & Nephew Orthopaedic Reconstruction Products
5. Smith & Nephew ENT Products