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UAB Osteca
Danes str. 47
LT-92108 Klaipeda
Lithuania

08 July 2024

Authorization letter

Smith & Nephew Orthopaedics AG, with its registered seat at Theilerstrasse 1A, 6300 Zug, Switzerland, VAT No.: CHE107345392, registered in Commercial Register Switzerland under registration number 3006853319 („Smith&Nephew"), hereby confirm that **UAB Osteca.**, a legal entity incorporated on the laws of Lithuania, having its registered office at 47 Danes, 92108, Klaipeda, pursuant to the Territory Sales Agreement between Smith & Nephew and UAB Osteca dated as of 01 January 2017, amended January 2018, 2019, 2020, 2021, 2022, 2023 and 2024 is authorized to undertake in the territory of Lithuania the following activities related to any or all of Smith & Nephew Sports Medicine (Endoscopy/ Arthrocare), Orthopaedic and Orthopaedic & Trauma and Advanced Wound Management Products listed:

- (a) to act as an authorized distributor of Smith & Nephew
- (b) to make decisions regarding prices, negotiating and concluding contracts for sale of products
- (c) to register products on behalf of Smith & Nephew as Smith & Nephew is the owner of the product registration
- (d) to market, promote and sell the Products
- (e) to train the hospital staff and conduct the demonstration on medical devices
- (f) to participate in tenders

The expiration date of TSA is December 31, 2024. In the event of termination or expire TSA for whatever reason, this letter shall also automatically cease to have effect.

DocuSigned by:
Alessandro Tozzi
Nome firmatario: Alessandro Tozzi
Motivo per la firma: Approvo il documento
Ora firma: 09-lug-2024 | 10:20:32 BST
8825CA4F92344580A240590EE818059A

DocuSigned by:
Sophie Mortamet
Signer Name: Sophie Mortamet
Signing Reason: I approve this document
Signing Time: 09-Jul-2024 | 10:58:22 BST
EE962841225D4440956A1B8E4071F

Signed for and on behalf of Smith & Nephew Orthopaedics AG

Name: Alessandro Tozzi
Title: VP Emerging Markets
CEE Date: 08.07.2024

Name: Sophie Mortamet
Title: Legal Director
Date: 08.07.2024

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

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



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:

DocuSigned by:
Piedad Pena

Date:

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

Signer Name: Piedad Pena
Signing Reason: I approve this document
Signing Time: 14-May-2024 | 20:30:53 BST

Print Name: Piedad Pena

5D46F116173D4FFFA4A7648880EAC17F

Title: Senior Regulatory Manager



Declaration of Conformity ENT and Spine Class II Devices	Document Number:	95005
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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

Smith & Nephew Endoscopy
76 S. Meridian Ave
Oklahoma City, OK 73107 USA

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

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. G1 077112 0040, Rev. 00, Exp. 26 May 2024

Design Examination Certificate Number N/A Class IIa & IIb
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 DIRECTIVE:

- 93/42/EEC FOR MEDICAL DEVICES, AS AMENDED BY 2007/47/EC, Annex II excluding Part 4.

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

DocuSigned by:
Piedad Pena
Signer Name: Piedad Pena
Signing Reason: I approve this document
Signing Time: 06-Jan-2022 | 19:04:28 GMT
5D46F116173D4FFFA4A7648880EAC17F

Piedad Pena

Regulatory Affairs Manager

06-Jan-2022 | 19:04:34 GMT

PRINTED NAME

TITLE

SIGNATURE

DATE OF ISSUE

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Template P/N 39616

Rev. K

ECN65000



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Catalogue Number	Labeled Name	Technical File #	EU Device Class	EU Device Rule	Date of Initial CE Mark	Date of Obsolescence
System 2000 Controller						
H2001-00	System 2000	TF-02748	Class IIb	Rule 9	20JAN1998	26JAN2017
H2075-00	System 2000	TF-02748	Class IIb	Rule 9	20JAN1998	26JAN2017
H2076-00	System 2000	TF-02748	Class IIb	Rule 9	20JAN1998	3JUN2016
H2078-00	System 2000	TF-02748	Class IIb	Rule 9	20JAN1998	26JAN2017
H2079-00	System 2000	TF-02748	Class IIb	Rule 9	20JAN1998	3JUN2016
H2076-59	System 2000	TF-02748	Class IIb	Rule 9	20JAN1998	30AUG2016
H2079-59	System 2000 Cable	TF-02748	Class IIb	Rule 9	20JAN1998	30AUG2016
02888-59	System 2000	TF-02748	Class IIb	Rule 9	20JAN1998	26APR2019
07869-58	System 2000	TF-02748	Class IIb	Rule 9	20JAN1998	30AUG2016
07869-59	System 2000	TF-02748	Class IIb	Rule 9	20JAN1998	30AUG2016
System 2000 Accessories						
H0970-02	Patient Cable	TF-02748	Class IIb	Rule 9	20JAN1998	21JUL2016
01652-59	Patient Cable	TF-02748	Class IIb	Rule 9	20JAN1998	24MAY2017
H2000-04	Footswitch	TF-02748	Class IIb	Rule 9	20JAN1998	3JUN2016
03390-59	Footswitch	TF-02748	Class IIb	Rule 9	20JAN1998	30AUG2016
02527-59	Power Cord	TF-02748	Class IIb	Rule 9	20JAN1998	24SEP2019
03389-99	Power Cord	TF-02748	Class IIb	Rule 9	20JAN1998	24SEP2019
03389-59	Power Cord	TF-02748	Class IIb	Rule 9	20JAN1998	26APR2019
H7510-00	Hand Switch Control	TF-02748	Class IIb	Rule 9	20JAN1998	7JUL2016
Coblator II System						
EC8000-01	Coblator II (120V)	TF-09806	Class IIb	Rule 9	22FEB2005	----
EC8001-01	Coblator II (240V)	TF-09806	Class IIb	Rule 9	14MAR2005	----
EC8000-59	Coblator II (120V) Refurbished	TF-09806	Class IIb	Rule 9	14MAR2005	----
EC8001-58	Coblator II (240V) Refurbished	TF-09806	Class IIb	Rule 9	14MAR2005	26JUL2016
11155-58	Coblator II (240V) Refurbished	TF-09806	Class IIb	Rule 9	19APR2011	----

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11155-59	Coblator II (120V) Refurbished	TF-09806	Class IIb	Rule 9	19APR2011	----
13546-58	Coblator II (240V) Refurbished	TF-09806	Class IIb	Rule 9	19APR2011	----
13546-59	Coblator II (120V) Refurbished	TF-09806	Class IIb	Rule 9	19APR2011	----
Coblator II System Accessories						
H3000-03	Shielded Foot Control	TF-09806	Class IIb	Rule 9	19APR2011	----
EA8000-00	Patient Cable	TF-09806	Class IIb	Rule 9	21JUL2003	16MAY2016
EA8002-00	Flow Valve	TF-09806	Class IIb	Rule 9	21JUL2003	----
H7500-01	Flow Control Unit Cable	TF-09806	Class IIb	Rule 9	21JUL2003	----
Irrigation Pump						
72290055	Irrigation Pump	TF-21215	Class IIb	Rule 9	14MAR2016	----
SIP001-00	Irrigation Pump	TF-21215	Class IIb	Rule 9	27MAY2008	6MAR2017
SIP001-01	Irrigation Pump	TF-21215	Class IIb	Rule 9	27MAY2008	6MAR2017
Irrigation Pump Accessories						
E3030-01	SAP Tube Clip	TF-21215	Class IIb	Rule 9	24JUL2015	----
Coblator IQ System						
ES9000-02	Coblator IQ System	TF-21890	Class IIb	Rule 9	13AUG2009	30AUG2016
ES9000-58	Coblator IQ System	TF-21890	Class IIb	Rule 9	9OCT2009	30AUG2016
ES9000-01	Coblator IQ System	TF-21890	Class IIb	Rule 9	1MAR2010	30JUL2018
ES9000-59	Coblator IQ System	TF-21890	Class IIb	Rule 9	1MAR2010	24OCT2018
WM9000-01	Coblator IQ System	TF-21890	Class IIb	Rule 9	3DEC2010	3JUN2016
WM9000-59	Coblator IQ System	TF-21890	Class IIb	Rule 9	3DEC2010	22JUL2016
SS9000-01	Coblator IQ Spine System	TF-21890	Class IIb	Rule 9	1NOV2011	3JUN2016
SS9000-59	Coblator IQ Spine System	TF-21890	Class IIb	Rule 9	1NOV2011	30AUG2016
34619-59	Coblator IQ Spine System	TF-21890	Class IIb	Rule 9	1NOV2011	30AUG2016
Coblator IQ Systems Accessory						
H3000-03	Shielded Foot Control	TF-21890	Class IIb	Rule 9	19APR2011	----

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Werewolf System Controller (RF20000) – Sports Medicine and ENT						
72290144	Werewolf Controller (RF20000)	TF-41317	Class IIb	Rule 9	31OCT2019	----
72290144S	Werewolf Controller (RF20000), Refurbished	TF-41317	Class IIb	Rule 9	31OCT2019	----
72290145	Werewolf Controller ENT Label Kit	TF-41317	Class IIb	Rule 9	03AUG2020	----
Werewolf System Controller Accessories (RF20000) – Sports Medicine and ENT						
72290007	Wired Foot Control Unit	TF-41317	Class IIb	Rule 9	19NOV2015	----
72290008	Wireless Foot Control Unit	TF-41317	Class IIb	Rule 9	19NOV2015	----
72290135	Irrigation Tube Set	TF-41317	Class IIa	Rule 9	17MAY2021	----
72290136	ENT Adapter	TF-41317	Class IIb	Rule 9	28SEP2020	----
72290081	Power Cord/ Manual – North America (Canada and Mexico)	TF-41317	Class IIb	Rule 9	18MAY2020	----
72290082	Power Cord/ Manual – Western Europe (Austria, Belgium, France, Germany, Italy, Luxembourg, The Netherlands)	TF-41317	Class IIb	Rule 9	18MAY2020	----
72290083	Power Cord/ Manual – Europe- Spanish (Bulgaria, Latvia, Malta, Portugal, Spain)	TF-41317	Class IIb	Rule 9	18MAY2020	----
72290084	Power Cord/ Manual – UK English	TF-41317	Class IIb	Rule 9	31OCT2019	----
72290086	Power Cord/ Manual – Australia	TF-41317	Class IIb	Rule 9	31OCT2019	----
72290087	Power Cord/ Manual - Scandinavia (Denmark, Finland, Norway, Sweden)	TF-41317	Class IIb	Rule 9	18MAY2020	----
72290088	Power Cord/ Manual – US English	TF-41317	Class IIb	Rule 9	31OCT2019	----
Werewolf+ System Controller						
72290146	Werewolf+ Coblation System	TF-41317-APL	Class IIb	Rule 9	21MAY2021	----
72290146S	Werewolf+ Coblation System (Service)	TF-41317-APL	Class IIb	Rule 9	21MAY2021	----
72290146F	Werewolf+ Coblation System (Refurbished)	TF-41317-APL	Class IIb	Rule 9	21MAY2021	----
Werewolf+ System Controller Accessories						
72290007	Wired Foot Control Unit	TF-41317	Class IIb	Rule 9	19NOV2015	----
72290008	Wireless Foot Control Unit	TF-41317	Class IIb	Rule 9	19NOV2015	----

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72290171	WEREWOLF + Power Cord/ Manual – N. America	TF-41317-APL	Class IIb	Rule 9	14SEP2021	----
72290172	WEREWOLF + Power Cord/ Manual – W. Europe	TF-41317-APL	Class IIb	Rule 9	14SEP2021	----
72290173	WEREWOLF + Power Cord/ Manual – EU Spanish	TF-41317-APL	Class IIb	Rule 9	14SEP2021	----
72290174	WEREWOLF + Power Cord/ Manual – EU English	TF-41317-APL	Class IIb	Rule 9	21MAY2021	----
72290176	WEREWOLF + Power Cord/ Manual – Australia	TF-41317-APL	Class IIb	Rule 9	21MAY2021	----
72290177	WEREWOLF + Power Cord/ Manual – Scandinavia	TF-41317-APL	Class IIb	Rule 9	14SEP2021	----
72290178	WEREWOLF + Power Cord/ Manual – US English	TF-41317-APL	Class IIb	Rule 9	21MAY2021	----
72290179	WEREWOLF + Power Cord/ Manual – Russia	TF-41317-APL	Class IIb	Rule 9	14SEP2021	----
72290180	WEREWOLF + Power Cord/ Manual – Korea	TF-41317-APL	Class IIb	Rule 9	14SEP2021	----
72290181	WEREWOLF + Power Cord/ Manual – Japan	TF-41317-APL	Class IIb	Rule 9	14SEP2021	----
72290182	WEREWOLF + Power Cord/ Manual – Switzerland	TF-41317-APL	Class IIb	Rule 9	14SEP2021	----
ENT Wands						
EIC4835-01	ReFlex Ultra PTR with Integrated Cable	TF-28199	Class IIb	Rule 9	1MAY2008	----
EIC4845-01	ReFlex Ultra 45 with Integrated Cable	TF-28199	Class IIb	Rule 9	15DEC2003	----
EIC4855-01	ReFlex Ultra 55 with Integrated Cable	TF-28199	Class IIb	Rule 9	15DEC2003	----
EIC4857-01	ReFlex Ultra SP with Integrated Cable	TF-28199	Class IIb	Rule 9	6JUN2008	----
EICA4835-01	ReFlex Ultra PTR with Integrated Cable	TF-28199	Class IIb	Rule 9	11DEC2012	----
EICA4845-01	ReFlex Ultra 45 with Integrated Cable	TF-28199	Class IIb	Rule 9	11DEC2012	----
EICA4855-01	ReFlex Ultra 55 with Integrated Cable	TF-28199	Class IIb	Rule 9	11NOV2012	----
EICA4857-01	ReFlex Ultra SP with Integrated Cable	TF-28199	Class IIb	Rule 9	11NOV2012	----
EIC5872-01	EVac 70 Xtra with Integrated Cable	TF-32658	Class IIb	Rule 9	21JUN2004	----
EIC5874-01	EVac 70 HP with Integrated Cable	TF-32658	Class IIb	Rule 9	12DEC2006	----
EICA5872-01	EVac 70 Xtra with Integrated Cable	TF-32658	Class IIb	Rule 9	11DEC2012	----
EICA5874-01	EVac 70 HP with Integrated Cable	TF-32658	Class IIb	Rule 9	11DEC2012	----
EIC7070-01	PROCISE LW Wand	TF-32757	Class IIb	Rule 9	20SEP2007	----
EIC7071-01	PROCISE MLW Wand	TF-32757	Class IIb	Rule 9	25FEB2011	----

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EIC8870-01	PROClSE EZ Wand	TF-32757	Class IIb	Rule 9	16JUN2006	----
EIC8872-01	PROClSE XP Wand	TF-32757	Class IIb	Rule 9	29JAN2007	----
EIC8875-01	PROClSE EZ-View Wand	TF-32757	Class IIb	Rule 9	1FEB2008	----
EIC8898-01	PROClSE MAX Wand	TF-32757	Class IIb	Rule 9	14OCT2010	----
EICA7070-01	PROClSE LW Wand	TF-32757	Class IIb	Rule 9	14DEC2012	----
EICA7071-01	PROClSE MLW Wand	TF-32757	Class IIb	Rule 9	14DEC2012	----
EICA8870-01	PROClSE EZ Wand	TF-32757	Class IIb	Rule 9	14DEC2012	----
EICA8872-01	PROClSE XP Wand	TF-32757	Class IIb	Rule 9	14DEC2012	----
EICA8875-01	PROClSE EZ-View Wand	TF-32757	Class IIb	Rule 9	14DEC2012	----
EICA8898-01	PROClSE MAX Wand	TF-32757	Class IIb	Rule 9	14DEC2012	----
EIC9820-01	EXClSE PDW Wand with integrated Cable	TF-34488	Class IIb	Rule 9	25APR2011	----
EIC6895-01	TURBINATOR Wand	TF-39691	Class IIb	Rule 9	21NOV2012	----
EICA6895-01	TURBINATOR Wand	TF-39691	Class IIb	Rule 9	7AUG2013	----
EIC2000-01	Head and Neck Coblation Wand	TF-41536	Class IIb	Rule 9	9MAY2012	13SEP2016
72290134	COBLATION HALO Wand	TF-75846	Class IIb	Rule 9	30OCT2019	----
Spine Products						
SCL600-01	Introducer Cannula, 17 Gauge Crawford, 6" Straight	TF-06447	Class IIa	Rule 6	11AUG2008	----
SCL800-01	Introducer Cannula, 17 Gauge Crawford, 8" Straight	TF-06447	Class IIa	Rule 6	11AUG2008	----
SDC03-01	COBLATOR IQ DC SPINEWAND	TF-24721	Class IIb	Rule 9	28AUG2009	----
SDLR03-01	COBLATOR IQ DLR SPINEWAND	TF-24721	Class IIb	Rule 9	28AUG2009	----
SDLG03-01	COBLATOR IQ DLG SPINEWAND	TF-24721	Class IIb	Rule 9	28AUG2009	----
K7908-01	PERC DC SPINEWAND Convenience Pack	TF-14882	Class IIb	Rule 9	28OCT2002	3MAY2016
K7925-01	PERC DLG SPINEWAND Convenience Pack	TF-14882	Class IIb	Rule 9	27AUG2004	----
K7920-01	PERC DLR SPINEWAND Convenience Pack	TF-14882	Class IIb	Rule 9	27AUG2004	----
SDC01-01	PERC DC SPINEWAND Convenience Pack	TF-14882	Class IIb	Rule 9	24NOV2008	----
KNS-1706-10	Spine Needle, 17 Gauge Crawford, 6" Straight	TF-14882	Class IIa	Rule 6	24SEP2006	----

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KNS-1708-10	Spine Needle, 17 Gauge Crawford, 8"	TF-14882	Class IIa	Rule 6	24SEP2006	3JUN2016
KNS-1904-10	Introducer Cannula, 19 Gauge Trocar, 3"	TF-14882	Class IIa	Rule 6	24SEP2006	----

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Certificate Of Completion

Envelope Id: 2A4A9F985554845A2ADE1C35233E610	Status: Completed
Subject: Please DocuSign: 95005_Rev AE_DoC_Class II ENT Spine_unsigned.pdf	
Source Envelope:	
Document Pages: 7	Signatures: 1
Certificate Pages: 1	Initials: 0
AutoNav: Enabled	Envelope Originator:
Envelopeld Stamping: Enabled	Sophia Poirier
Time Zone: (UTC) Dublin, Edinburgh, Lisbon, London	TJ Smith & Nephew Limited
	101 Hesse Road
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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	05-Jan-2022 15:26
Certified Delivered	Security Checked	06-Jan-2022 19:03
Signing Complete	Security Checked	06-Jan-2022 19:04
Completed	Security Checked	06-Jan-2022 19:04
Payment Events	Status	Timestamps