

Declaration of Conformity ENT Class I Sterile Devices	Document Number:	95004
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Manufacturer's Name & Address: ArthroCare Corporation
7000 West William Cannon Drive
Austin, TX 78735 USA

Manufacturing Facilitie(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 0032

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: 15 Feb 2019

Signature: 

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Name: Kulsum Master

Title: Director, Regulatory Affairs

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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			
605-60100S	Ventura Sinus Dilation Balloon	TF-010	Class 1 Sterile	Rule 5	II	4	48140	12MAR2011	N/A
RR 300	Rapid Rhino ^o 3 cm Riemann Nasal Dressing	TF-22959	Class 1 Sterile	Rule 5	V	3	31919	08APR2008	N/A
RR 400	Rapid Rhino ^o 4 cm Riemann Nasal Dressing	TF-22959	Class 1 Sterile	Rule 5	V	3	31919	08APR2008	N/A
RR 450	Rapid Rhino ^o 4.5 cm Anterior	TF-22959	Class 1 Sterile	Rule 5	V	3	12699	08APR2008	N/A
RR 500	Rapid Rhino ^o 5.5 cm Goodman Nasal Dressing	TF-22959	Class 1 Sterile	Rule 5	V	3	31919	08APR2008	N/A
RR 530	Rapid Rhino ^o 5.5 cm Rapid-Pac	TF-22959	Class 1 Sterile	Rule 5	V	3	31919	08APR2008	N/A
RR 550	Rapid Rhino ^o 5.5 cm Anterior	TF-22959	Class 1 Sterile	Rule 5	V	3	12699	08APR2008	N/A
RR 551	Rapid Rhino ^o 5.5 cm Anterior Airway	TF-22959	Class 1 Sterile	Rule 5	V	3	12699	08APR2008	N/A
RR 552	Rapid Rhino ^o 5.5 cm Bilateral	TF-22959	Class 1 Sterile	Rule 5	V	3	12699	08APR2008	N/A
RR 555	Rapid Rhino ^o 5.5 cm Bilateral with Airway	TF-22959	Class 1 Sterile	Rule 5	V	3	12699	08APR2008	N/A
RR 600	Rapid Rhino ^o SINU-KNIT ^o	TF-22959	Class 1 Sterile	Rule 5	V	3	31919	08APR2008	N/A
RR 650	Rapid Rhino ^o SINU-FOAM ^o Dressing	TF-22959	Class 1 Sterile	Rule 5	V	3	31919	08APR2008	N/A
RR 750	Rapid Rhino ^o 7.5 cm Ant/Posterior	TF-22959	Class 1 Sterile	Rule 5	V	3	12699	08APR2008	N/A
RR 751	Rapid Rhino ^o 7.5 cm Ant/Posterior with Airway	TF-22959	Class 1 Sterile	Rule 5	V	3	12699	08APR2008	N/A
RR 752	Rapid Rhino ^o 7.5 cm Ant/Posterior Bilateral	TF-22959	Class 1 Sterile	Rule 5	V	3	12699	08APR2008	N/A
RR 755	Rapid Rhino ^o 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 ^o 8 cm Nasal Dressing	TF-22959	Class 1 Sterile	Rule 5	V	3	31919	08APR2008	N/A
RR 900	Rapid Rhino ^o Nasal Catheter Posterior Epistaxis	TF-22959	Class 1 Sterile	Rule 5	V	3	12699	06OCT2009	N/A
RR 1000	NASASTENT ^o	TF-45154	Class 1 Sterile	Rule 5	V	3	31919	21JUL2014	N/A

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