SAO Y BẢN CHÍNH
Ngày 26 Tháng 7 Năm 2017

ArthroCare®

Declaration of Conformity

TF- 22959

SMITH & NEPHEW PTE. LIMITED SINGAPORE
VĂN PHÒNG ĐẠI DIỆN TẠI TP. HỒ CHÍ MINH

Manufacturer:	ArthroCare Corporation 7000 West William Cannon Drive Austin, TX 78735-8531 USA
Manufacturing Facilities:	7000 West William Cannon Drive Austin, TX 78735 USA B32.1, St2, Zona Franca Coyol Coyol, Costa Rica, 20101 Costa Rica 502 Parkway, Global Park La Aurora, Heredia Costa Rica 2301 E Saint Elmo Rd Suite 110 Austin, Texas 78744 USA
European Authorized Representative:	Smith & Nephew York Science Park Heslington, York YO10 5DF United Kingdom +44 (0) 1926 482400 ec.rep@smith-nephew.com
Name of Device:	See Attachment A of the Declaration of Conformity
Catalogue Number(s):	See Attachment A of the Declaration of Conformity
Classification, Rule:	Class I (sterile) per MDD Annex IX, Rule 5
GMDN Code:	See Attachment A of the Declaration of Conformity
CE Certificate No.	G2S 16 03 77112 020

WE HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCTS MEET THE PROVISIONS OF THE FOLLOWING COUNCIL DIRECTIVES :

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

THIS DECLARATION OF CONFORMITY IS ISSUED UNDER THE SOLE RESPONSIBILITY OF THE COMPANY. ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER.

Notified body:	TÜV SÜD Product Services GmbH Zertifizierstelle Ridlerstrasse 65 80339 Munchen, Germany CE 0123
Date CE Mark was affixed:	See Attachment A of the Declaration of Conformity
Place Issued:	Austin, Texas
Date Issued:	22 August 2016
Signature:	Shirley Hyink
Name:	Shirley Hyink
Title:	Regulatory Affairs, Director

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Attachment A

Catalog Number	Device Description	GMDN Code	Date of Initial CE Mark
RR 450	4.5 cm Anterior	12699	08 Apr. 2008
RR 550	5.5cm Anterior	12699	08 Apr. 2008
RR 750	7.5cm Anterior/Posterior	12699	08 Apr. 2008
RR 552	5.5cm Anterior-Bilateral	12699	08 Apr. 2008
RR 752	7.5cm Anterior-Bilateral	12699	08 Apr. 2008
RR 551	5.5cm Anterior-Airway	12699	08 Apr. 2008
RR 555	5.5cm Anterior-Airway, Bilateral	12699	08 Apr. 2008
RR 751	7.5cm Anterior/Posterior- Airway	12699	08 Apr. 2008
RR 755	7.5cm Anterior/Posterior-Airway, Bilateral	12699	08 Apr. 2008
RR 55002	5.5cm 2-pack	12699	08 Apr. 2008
RR 75002	7.5cm 2-pack	12699	08 Apr. 2008
RR 300	Riemann 3cm	31919	08 Apr. 2008
RR 400	Riemann 4cm	31919	08 Apr. 2008
RR 500	Goodman 5.5cm	31919	08 Apr. 2008
RR 800	Mannheim 8cm	31919	08 Apr. 2008
RR 530	Rapid Pac 5.5cm Anterior	31919	08 Apr. 2008
RR 600	Sinu-Knit	31919	08 Apr. 2008
RR 650	Stammberger Sinu-Foam	31919	08 Apr. 2008
RR 900	Nasal Catheter, Posterior	12699	06 Oct. 2009

SAO Y BẢN CHÍNH
Ngày 26 Tháng 7 Năm 2017

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TF- 45154

SMITH & NEPHEW PTE. LIMITED SINGAPORE
VĂN PHÒNG ĐẠI DIỆN TẠI TP. HỒ CHÍ MINH

Manufacturer:	ArthroCare Corporation 7000 West William Cannon Drive Austin, TX 78735-8531 USA
Manufacturing Facilities:	7000 West William Cannon Drive Austin, TX 78735-8531 USA 2301 E Saint Elmo Rd Suite 110 Austin, Texas 78744 USA
European Authorized Representative:	Smith & Nephew York Science Park Heslington, York YO10 5DF United Kingdom +44 (0) 1926 482400 ec.rep@smith-nephew.com
Name of Device:	NASASTENT®
Catalogue Number(s):	RR1000
Classification, Rule:	Class I (sterile) per MDD Annex IX, Rule 5
GMDN Code:	31919
CE Certificate No.	G2S 16 03 77112 020
Conformity Assessment Route:	Annex V, section 3 of MDD

WE HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCTS MEET THE PROVISIONS OF THE FOLLOWING COUNCIL DIRECTIVES (NOTE: EDIT LIST OF DIRECTIVES AS APPLICABLE):

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

THIS DECLARATION OF CONFORMITY IS ISSUED UNDER THE SOLE RESPONSIBILITY OF THE COMPANY. ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER.

Notified body:	TÜV SÜD Product Services GmbH Zertifizierstelle Ridlerstrasse 65 80339 Munchen, Germany CE 0123
Date CE Mark was affixed:	21 July 2014
Place Issued:	Austin, Texas
Date Issued:	22 August 2016
Signature:	Shirley Hyink
Name:	Shirley Hyink
Title:	Director, Regulatory Affairs