ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC Certificate

Production Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 16 03 77112 020

Manufacturer:

ArthroCare Corporation
7000 West William Cannon Drive
Austin TX 78735-8531
USA

EC-Representative:

Smith & Nephew
York Science Park
Heslington
York YO10 5DF
UNITED KINGDOM

Product Category(ies):

Sterile Dilator Cannulae Seal Caps, Nasal Catheters and Nasal Dressings, Straps for Ankle Distractors and Sinus Dilation Balloon and Instruments

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

Report No.: 72111156

Valid from: 2016-05-19
Valid until: 2020-03-19

Date, 2016-05-19

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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Facility(ies):

ArthroCare Corporation
7000 West William Cannon Drive, Austin TX 78735-8531, USA

ArthroCare Corporation
15285 Alton Parkway, Suite 200, Irvine CA 92618, USA

ArthroCare Corporation
2301 E. Saint Elmo Road, Suite 110, Austin TX 78744, USA

ArthroCare Corporation
502 Parkway, Global Park, La Aurora, Heredia, COSTA RICA

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