



Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
www.zlg.de  
ZLG-BS-244.10.08



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 077112 0041 Rev. 00**

## Manufacturer

### ArthroCare Corporation

7000 West William Cannon Drive  
Austin TX 78735-8531  
USA

## Product Category(ies):

**Sterile Dilator Cannulae Seal Caps,  
Nasal Catheters and Nasal Dressings,  
Straps for Ankle Distractors.**

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.:** 72154321

**Valid from:** 2020-02-12

**Valid until:** 2024-05-26

**Date,** 2020-02-12

Christoph Dicks  
Head of Certification/Notified Body

TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD  
 ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ CERTIFICADO ◆ CERTIFICAT



Benannt durch/Designated by  
 Zentralstelle der Länder  
 für Gesundheitsschutz  
 bei Arzneimitteln und  
 Medizinprodukten  
 www.zlg.de  
 ZLG-BS-244.10.08



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 077112 0041 Rev. 00**

## Facility(ies):

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

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

.



Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
www.zlg.de  
ZLG-BS-244.10.08



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 077112 0041 Rev. 00**

## Manufacturer

### ArthroCare Corporation

7000 West William Cannon Drive  
Austin TX 78735-8531  
USA

## Product Category(ies):

**Sterile Dilator Cannulae Seal Caps,  
Nasal Catheters and Nasal Dressings,  
Straps for Ankle Distractors.**

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.:** 72154321

**Valid from:** 2020-02-12

**Valid until:** 2024-05-26

**Date,** 2020-02-12

Christoph Dicks  
Head of Certification/Notified Body



Benannt durch/Designated by  
 Zentralstelle der Länder  
 für Gesundheitsschutz  
 bei Arzneimitteln und  
 Medizinprodukten  
 www.zlg.de  
 ZLG-BS-244.10.08



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 077112 0041 Rev. 00**

## Facility(ies):

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

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

./.

TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD  
 ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ CERTIFICADO ◆ CERTIFIKAT ◆ CERTIFICATE ◆ ZERTIFIKAT ◆ CERTIFICATE