ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

CERTIFICATE

No. QS6 003953 0005 Rev. 00

Certificate Holder: **Contura International A/S**
Sydmarken 23
2860 Soeborg
DENMARK

Certification Mark:

Scope of Certificate: **Design, Development and Manufacture of Implantable Hydrogel Products; Design, Development and Manufacture of Urethral Bulking Procedure Packs; Design, Development and Manufacture of Guidance Devices intended to be used with Implantable Hydrogel Products**

Standard(s): **ISO 13485:2016**

Regulatory Authority(ies): **Australia TGA, Health Canada. See attached for listing of specific regulatory requirements.**

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. Validity of this certificate can be obtained by visiting the website www.tuvsud.com/ps-cert
TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

DUNS No: **30-820-0307**

Effective Date: **2020-07-20**

Expiry Date: **2023-07-19**

Date of Issue: 2020-07-28

(Tina Israel)
Manager, US Certification Body,
Medical and Health Services

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C E R T I F I C A T E

No. QS6 003953 0005 Rev. 00

Regulatory Requirements: **Audit/Certification Criteria**

Australia
Therapeutic Goods (Medical Devices) Regulations 2002 - Schedule 3, Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure

Canada
- Medical Device Regulations – Part 1- SOR 98/282

Facility(ies):
Contura International A/S
Sydmarken 23, 2860 Soeborg, DENMARK

Facility Scopes:
Design, Development and Manufacture of Implantable Hydrogel Products; Design, Development and Manufacture of Urethral Bulking Procedure Packs; Design, Development and Manufacture of Guidance Devices intended to be used with Implantable Hydrogel Products
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