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

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

Product Service

EU Technical Documentation Assessment Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapter II
(Implantable Class IIb Devices and Class III Devices)

No. G70 003953 0006 Rev. 00

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

SRN Manufacturer: DK-MF-000002018

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has drawn up and presented a Technical Documentation according to Annex II and III of the Regulation (EU) 2017/745 on medical devices. Details on devices covered by the Technical Documentation are described on the following page(s). The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The technical documentation assessment included an assessment of the clinical evaluation assessment. The conformity assessment has been carried out according to Annex IX chapter II of this regulation with a positive result.
Changes to the approved device, where such changes could affect the safety and performance of the device or the conditions prescribed for use of the device, shall require approval from the notified body TÜV SÜD Product Service GmbH. In order to place the devices on the market with CE-marking, an EU Quality Management System Certificate pursuant to Annex IX chapters I and III is necessary in addition to this EU Technical Documentation Assessment Certificate. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G70 003953 0006 Rev. 00

Report No.: 713205788

Valid from: 2022-11-09
Valid until: 2027-11-08

Issue date: 2022-11-09

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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No. G70 003953 0006 Rev. 00

Classification:	IIb
Device Group:	U070199 - INTERNAL SYSTEMS FOR THE TREATMENT OF INCONTINENCE - OTHER
Basic UDI-DI:	5704101BulkamidCG
Intended Purpose:	Bulkamid Hydrogel is intended to be used as a urethral bulking agent for the treatment of female urinary incontinence where the stress component is significant
Device(s):	Bulkamid Hydrogel 50009

The validity of this certificate depends on conditions and/or is limited to the following: ./.

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