



EU Quality Management System Certificate (MDR)

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

No. G12 003953 0009 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 established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system 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 conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.

The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH.

In order to place the devices on the market with CE-marking, an EU Technical Documentation Assessment Certificate pursuant to Annex IX chapter II is necessary in addition to this EU Quality Management System 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:G12 003953 0009 Rev. 00](http://www.tuvsud.com/ps-cert?q=cert:G12_003953_0009_Rev.00)

Report No.: 713192778

Valid from: 2022-12-12

Valid until: 2027-12-11

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2022-12-12



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Classification: IIb
Device Group: U070199 - INTERNAL SYSTEMS FOR THE TREATMENT OF INCONTINENCE - OTHER
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

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