



Certificate

No. Q5 003953 0001 Rev. 03

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

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

See Scope of Certificate

Certification Mark:



Scope of Certificate: **Design, development and manufacture of sterile implantable hydrogel products used in the areas of non-resorbable filling and reconstruction devices and systems for the treatment of incontinence.**
Design, development and manufacture of urethral bulking procedure packs.
Design, development and manufacture of sterile Bulkamid Needle and sterile Bulkamid Rotatable Sheath for the treatment of incontinence.

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). 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:Q5 003953 0001 Rev. 03](http://www.tuvsud.com/ps-cert?q=cert:Q5_003953_0001_Rev.03)

Report No.: 713225242
Valid from: 2023-04-05
Valid until: 2026-02-09



Date, 2023-04-05

Christoph Dicks
Head of Certification/Notified Body