EU Quality Management Certificate

This is to certify that the company

Fasciotens GmbH

Moltkeplatz 1
45138 Essen
Germany

SRN: DE-MF-000005082

has established, implemented and maintains a Quality Management System in accordance with

Annex IX, Chapter I and III of the Regulation (EU) 2017/745

Conformity Assessment based on a Quality Management System and on Assessment of Technical Documentation

for the device categories and products listed in the Annex of this certificate.

The conformity of the Quality Management System has been verified in an audit and is subject to regular surveillance in accordance with Annex IX, Chapter 1, Section 3.
Limitations to this certificate are listed in the Annex.

Devices listed in the Annex may bear the CE marking with the identification number of the Notified Body (0297).

For placing of devices of class III and devices class IIb implantable according to Article 52(4) subparagraph 2 listed in the Annex on the market, an additional certificate according to Annex IX, Chapter II is required.

Certificate registration no.	31618427 MDR2017Q
Certificate ID	1000195286
Effective date	2024-08-30
Expiry date	2029-03-06
Frankfurt am Main,	2024-08-30

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-094

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Michael Bothe
Head of Certification Body
(active medical devices)

Szymon Kurdyn
Head of Certification Body
(non-active medical devices)

Accredited Body: DQS Medizinprodukte GmbH, August-Schanz-Str. 21, 60433 Frankfurt am Main
DQS Medizinprodukte GmbH is a Notified Body according to Regulation (EU) 2017/745 of the Council concerning medical devices with the Identification Number 0297.
The validity of the certification can only be verified by the QR-code.

420.90 Version 6.0

Annex to EU Quality Management Certificate
SRN of Manufacturer: DE-MF-000005082
Certificate ID: 1000195286

Device categories and variants covered by this certificate:

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	fasciotens®Abdomen (REF: A020)
Risk classification:	Is
Basic-UDI-DI:	426065064TEQW
Intended purpose:	Prevention of fascial retraction in open abdomen and stretching of the abdominal wall/fascia in cases of existing or prior loss of abdominal wall/fascia.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	fasciotens®Hernia (REF: H010)
Risk classification:	Is
Basic-UDI-DI:	426065064TEQW
Intended purpose:	Prevention of fascial retraction in open abdomen and stretching of the abdominal wall/fascia in cases of existing or prior loss of abdominal wall/fascia.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	fasciotens®Pediatric (REF: P010)
Risk classification:	Is
Basic-UDI-DI:	426065064TEQW
Intended purpose:	Prevention of fascial retraction in open abdomen and stretching of the abdominal wall/fascia in cases of existing or prior loss of abdominal wall/fascia.

Examinations and tests performed:

31618427_A213142MED_01 dated 2024-02-12
31618427_A213142MED_02 Pediatric dated 2024-02-12
31618427_ A213142MED_03 revised Auditreport dated 2024-04-28

Further conditions for or limitations to the validity of the certificate:

In case of products that are placed on the market in sterile condition, the involvement of the Notified Body in the conformity assessment procedure is limited to the aspects of manufacture concerned with securing and maintaining sterile condition.

Reference to previous certificates:

Revision	Date of Issue	Certificate-ID	Description of change
01	2024-03-07	1000131270	Adjustment of product names
02	2024-04-04	1000170362	Report reference to the revised audit report