



CERTIFICATE



This is to certify that the company

Fasciotens GmbH

Moltkeplatz 1
45138 Essen
Germany

with the organizational units/sites as listed in the annex

has implemented and maintains a **Quality Management System**.

Scope:

Development, manufacture, storage and distribution of tissue expansion instruments and associated non-sterile patient positioning and instrument holding systems

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of the following standard:

DIN EN ISO 13485 : 2016 + AC : 2017-07
EN ISO 13485 : 2016 + AC : 2018
ISO 13485 : 2016

Certificate registration no.	31618427 MP2016
Certificate unique ID	1000189528
Effective date	2024-08-02
Expiry date	2027-02-11
Frankfurt am Main	2024-08-02



DQS IS A MEMBER OF



DQS Medizinprodukte GmbH

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Managing Director

Szymon Kurdyn
Product Manager

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The validity of the certification can only be verified by the QR-code.



Annex to certificate
Certificate registration No.: 31618427 MP2016
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Effective date: 2024-08-02

Fasciotens GmbH

Moltkeplatz 1
45138 Essen
Germany

Location

Scope

31618427
Fasciotens GmbH
Moltkeplatz 1
45138 Essen
Germany

Registered office (excluding MD-related activities)

31618428
Fasciotens GmbH
Operational place of business
Aachener Straße 1053-1055
50858 Köln
Germany

Development, manufacture and distribution of tissue expansion instruments and associated non-sterile patient positioning and instrument holding systems

31618429
Fasciotens GmbH
Lager
Sachsstraße 16
50259 Puhlheim
Germany

Storage and dispatch of medical devices