



# 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 and distribution of tissue expansion instruments and associated nonsterile 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	1000131265
Effective date	2024-02-12
Expiry date	2027-02-11
Frankfurt am Main	2024-02-12



DOS IS A MEMBER OF





DQS Medizinprodukte GmbH

We luna

Sigrid Uhlemann Managing Director

S.Kudyn

Szymon Kurdyn Product Manager

4/4\_90e Version 3.0

August-Schanz-Straße 21, 60433 Frankfurt am Main, Tel. +49 (0) 69 95427-300, <u>info-med@dqs.de</u> The validity of this certificate can only be verified by the QR-code.





#### Annex to certificate Certificate registration No.: 31618427 MP2016 Certificate unique ID: 1000131265 Effective date: 2024-02-12

### **Fasciotens GmbH**

Moltkeplatz 1 45138 Essen Germany

Location

**31618427 Fasciotens GmbH** Moltkeplatz 1 45138 Essen Germany

31618428

Fasciotens GmbH Aachener Straße 1053-1055 50858 Köln Germany

31618429 Fasciotens GmbH Sachsstraße 16 50259 Puhlheim Germany Scope

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

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

Storage and dispatch of medical devices