

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

FSSB Chirurgische Nadeln GmbH

Allmendweg 2
79798 Jestetten
Germany

Holds Certificate Number:

MD 632328

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

Design, manufacture and distribution of sterile surgical needles, absorbable and non-absorbable surgical sutures and pledgets.
Entwicklung, Herstellung und Vertrieb von sterilen chirurgischen Nadeln, resorbierbarem und nicht-resorbierbarem chirurgischem Nahtmaterial und Nahtpolster.

Previous certificate expired on 05.07.2018.
Recertification audit ended 17.05.2018.



For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2016-08-22

Latest Revision Date: 2018-07-10

Effective Date: 2018-07-10

Expiry Date: 2021-07-05

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