EU Quality Management System Certificate

We hereby certify the company

Hofer GmbH & Co KG
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Austria

the introduction and application of a quality management system in accordance with Annex IX, Chapter I and III of Regulation (EU) 2017/745 for conformity assessment.

An audit by mdc has proven that this quality management system meets the following requirements:

Annex IX – Chapter I (Quality Management System)

of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.

Surveillance is carried out in accordance with Annex IX, Section 3 of Regulation (EU) 2017/745.

This certificate from mdc medical device certification GmbH (Notified Body 0483) consists of 3 pages. Details about the devices covered as well as further information and conditions are contained on the following pages.

Valid from	2024-12-17	Registration No.	D4001600009
Valid until	2027-08-10	Report No.	P23-01178-278062

Stuttgart, 2024-12-17

Notified Body

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-098

Devices:

Bone plates, sterile/non-sterile

Intended purpose: Osteosynthesis implants are intended for stabilization and fixation of reduced bone fragments during natural fracture healing

Risk class: IIb

Bone screws, steril/non-sterile

Intended purpose: Osteosynthesis implants are intended for stabilization and fixation of reduced bone fragments during natural fracture healing

Risk class: IIb

Bone drill, non-sterile

Risk class: IIa

Trials, depth measuring gauges, measuring rods

Risk class: IIa

Screwdriver (inserts), holding sleeves for screwdrivers

Risk class: IIa

Drill guide instruments, insertion instruments, extraction instruments, cutting instruments, targeting instruments

Risk class: IIa

Bone nails, sterile/non-sterile

Intended purpose: Osteosynthesis implants are intended for stabilization and fixation of reduced bone fragments during natural fracture healing

Risk class: IIb

Reusable surgical instruments (to manipulate tissue and bone material during implantation and explantation of osteosynthesis implants)

Risk class: I (reusable)

Notes:

In the case of class I devices that are reusable surgical instruments the involvement of mdc is limited to the aspects relating to the reuse of the device, in particular cleaning, disinfection, sterilization, maintenance and functional testing as well as the related instructions for use.

For the placing on the market of class III and IIb implantable devices (except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors within the meaning of Regulation (EU) 2017/745, Art. 52 (4), 2nd paragraph and with the exception of custom-made devices of class III), an EU technical documentation assessment certificate is also required.

The certificate is based on the previous certificate

D4001600006 (2023-01-12)
D4001600008 (2024-01-05)

with the following changes to D4001600008:
Reclassification of the product group from class Ir to IIa:
- Screwdrivers (inserts), holding sleeves for screwdrivers
- (Drilling) guiding, insertion, extraction, cutting instruments, targeting instruments

Supplementary product group Class Ir:
- Reusable surgical instruments (to manipulate tissue and bone material during implantation and explantation of osteosynthesis implants)