EU Quality Management System Certificate

We hereby certify the company

devemed GmbH
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Germany

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 4 pages. Details about the devices covered as well as further information and conditions are contained on the following pages.

Valid from	2025-12-05	Registration No.	D1150500008
Valid until	2028-05-29	Report No.	P24-01534-317047

Stuttgart, 2025-12-05

Notified Body

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

Devices:

Reusable surgical instruments:
Surgical Scissors (Standard)
Micro-Scissors
Ligature Scissors
Scalpel Handles & Holders
Gingivektomy Knives
dev-lux Instruments
Periotomes
Syndesmotomes
Desmotomes
Surgical Curettes
Sinus Curettes
Sharp Spoons
Chisels
Osteotomes
Handles for Chisel- & Ostoeotome attachements
Periodontal Files (Periodontal Surgery)
Bone Files (surgical)
Periosteal Elevators
Bone Rongeurs
Bone Cutting Forceps
Bone Scrapers
Excavators
Needleholders (Ring handle)
Needleholders (Rotary Catch)
Micro-Needleholders
Extracting Forceps
Tweezers
Haemostatic Forceps
Nerve Canal Pliers
Tweezers (aids)
Dressing (Gauze) Forceps
Bone holding Forceps
Tissue grasping Forceps
Retractors
Sinus-Lift Elevators
Perio-Surgery-Instruments, retracting
Root Elevators (Standard)
Root Elevators (T-Handle)
Periolux
Pivot-Point

Root Fragment Elevators
Root Screws
Wound Pluggers
Endodontic Pluggers

Risk class: I (reusable)

Microscrews / Titanium

Intended purpose: Microscrews for fixing bone grafts and bone graft substitutes for augmentation and/or reconstruction of jaw and facial bones.

Risk class: IIb

Microscrews / INOX

Intended purpose: Microscrews for fixing bone grafts and bone graft substitutes for augmentation and/or reconstruction of jaw and facial bones.

Risk class: IIb

Pins

Intended purpose: Pins for fixing membranes and meshes during augmentation and/or reconstruction of jaw and facial bones.

Risk class: IIb

Meshes

Intended purpose: Meshes for fixing bone grafts and bone graft substitutes for augmentation and/or reconstruction of jaw and facial bones.

Risk class: IIb

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

D1150500006 (2024-09-19)

with the following changes to D1150500006:
Supplemented by:
Microscrews / Titanium, Microscrews / INOX, Pins, Meshes