

EU Quality Management System Certificate

We hereby certify the company

HIPP Medical AG
Wilhelmstraße 19
78600 Kolbingen
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 2 pages. Details about the devices covered as well as further information and conditions are contained on the following pages.

Valid from 2025-10-01
Valid until 2029-01-12

Registration No. D1225500009
Report No. P22-01869-255287

Stuttgart, 2025-10-01



Notified Body



Devices:

Titanium Pins and Micro Screws

Intended purpose: Titanium pins and micro screws are used to fix resorbable and non-resorbable membranes during regenerative and surgical procedures in the field of oral and maxillofacial surgery

Risk class: IIb

Kirschner Wires and Guide Wires, sterile and non-sterile

Intended purpose: Temporary repositioning and guide wires for surgery, closed reduction and fixation of fractures, osteotomies, fusions of the upper and lower extremities

Risk class: IIb

Drills, Burs/Reamers and Tappers, sterile and non-sterile

Risk class: IIa

Notes:

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.