EU Quality Management System Certificate

Certificate no.	Final Assessment Report no.	Effective date	Expiry date
6608GB448230109	6608IA14F	2023-01-09	2027-01-12

This is to certify that the quality system of

HiPer Medical AG

Ziegeleistraße 7, 16727 Oberkrämer, Germany

SRN: DE-MF-000008894

For design, production, and final product inspection/testing of

Medical devices/groups of medical devices listed on the following pages

Has been assessed and found to comply with respect to

The conformity assessment procedure described in Annex IX Chapter I of Regulation (EU) 2017/745 on Medical Devices

Any applicable limitations for certain medical devices are included in the following list or recorded in the final assessment report. This certification is subject to surveillance by DNV MEDCERT.

Place and date
Hamburg, 2023-01-09

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-096

For the issuing office
DNV MEDCERT GmbH – Notified Body 0482
Pilatuspool 2, 20355 Hamburg, Germany

Lorenz Runge
Chief Certification

The certificate is only valid when provided entirely with all of its pages. To verify the validity of this certificate, contact info@medcert.de

Certificate no.: 6608GB448230109
Place and date: Hamburg 2023-01-09

Products covered by this certificate

Class III medical devices

For placing on the market of class III medical devices covered by this certificate, an additional EU Technical Documentation Assessment Certificate according to Annex IX Chapter II of Regulation (EU) 2017/745 is required, which also contains the exact determination of medical devices covered by certification.

Category	Medical devices/groups of medical devices
MDN 1102	Non-active osteo- and orthopaedic implants