

EU Technical Documentation Assessment Certificate

Certificate no.
12970GB450230109

Final Assessment Report no.
12970IA13F

Effective date
2023-01-09

Expiry date
2026-11-29

This is to certify that
Medical devices listed on the following pages

Manufactured by

HiPer Medical AG

Ziegeleistraße 7, 16727 Oberkrämer, Germany
SRN: DE-MF-000008894

Have been assessed and found to comply with respect to

**Technical Documentation Assessment as described in Annex IX
Chapter II 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 certificate assumes that DNV MEDCERT has to be informed about any changes of the assessed device. Changes need further approval by DNV MEDCERT.

For conditions or for limitations to the validity refer to the relevant final assessment report. Examinations and tests performed, e. g. reference to relevant common specifications, harmonised standards, test reports and audit report(s), are recorded in the relevant reports. For placing on the market of the medical devices covered by this certificate, an additional EU Quality Management System Certificate according to Annex IX Chapter I of Regulation (EU) 2017/745 is required.

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

Products covered by this certificate

Class	III
MDN	1102
Basic UDI-DI	426043607
Intended purpose	modular bearing components for hip implants
Model (REF#)	Medical device name
110000	ELEC® femoral head Ø 28-12/14S (-3,5 mm)
110010	ELEC® femoral head Ø 28-12/14M (±0 mm)
110020	ELEC® femoral head Ø 28-12/14L (+3,5 mm)
110030	ELEC® femoral head Ø 32-12/14S (-4 mm)
110040	ELEC® femoral head Ø 32-12/14M (±0 mm)
110050	ELEC® femoral head Ø 32-12/14L (+4 mm)
110070	ELEC® femoral head Ø 36-12/14S (-4 mm)
110080	ELEC® femoral head Ø 36-12/14M (±0 mm)
110090	ELEC® femoral head Ø 36-12/14L (+4 mm)
110100	ELEC® femoral head Ø 36-12/14XL (+8 mm)
110110	ELEC® femoral head Ø 40-12/14S (-4 mm)
110120	ELEC® femoral head Ø 40-12/14M (±0 mm)
110130	ELEC® femoral head Ø 40-12/14L (+4 mm)
110140	ELEC® femoral head Ø 40-12/14XL (+8 mm)
110230	ELEC® plus femoral head Ø 28-12/14S (-3,5 mm)
110240	ELEC® plus femoral head Ø 28-12/14M (±0 mm)
110250	ELEC® plus femoral head Ø 28-12/14L (+3,5 mm)
110260	ELEC® plus femoral head Ø 32-12/14S (-4 mm)
110270	ELEC® plus femoral head Ø 32-12/14M (±0 mm)
110280	ELEC® plus femoral head Ø 32-12/14L (+4 mm)
110291	ELEC® plus femoral head Ø 32-12/14XL (+7 mm)
110300	ELEC® plus femoral head Ø 36-12/14S (-4 mm)
110310	ELEC® plus femoral head Ø 36-12/14M (±0 mm)
110320	ELEC® plus femoral head Ø 36-12/14L (+4 mm)
110330	ELEC® plus femoral head Ø 36-12/14XL (+8 mm)
110340	ELEC® plus femoral head Ø 40-12/14S (-4 mm)
110350	ELEC® plus femoral head Ø 40-12/14M (±0 mm)
110360	ELEC® plus femoral head Ø 40-12/14L (+4 mm)
110370	ELEC® plus femoral head Ø 40-12/14XL (+8 mm)
120000	ELEC® plus acetabular insert 28/35-18
120020	ELEC® plus acetabular insert 28/37-18
120040	ELEC® plus acetabular insert 28/39-18
120050	ELEC® plus acetabular insert 28/41-18
120060	ELEC® plus acetabular insert 28/42-18
120070	ELEC® plus acetabular insert 28/44-18
120080	ELEC® plus acetabular insert 28/46-18
120090	ELEC® plus acetabular insert 28/48-18

120100	ELEC@plus acetabular insert 28/50-18
120110	ELEC@plus acetabular insert 28/52-18
120120	ELEC@plus acetabular insert 28/54-18
120210	ELEC@plus acetabular insert 32/39-18
120220	ELEC@plus acetabular insert 32/41-18
120230	ELEC@plus acetabular insert 32/42-18
120240	ELEC@plus acetabular insert 32/44-18
120250	ELEC@plus acetabular insert 32/46-18
120260	ELEC@plus acetabular insert 32/48-18
120270	ELEC@plus acetabular insert 32/50-18
120280	ELEC@plus acetabular insert 32/52-18
120290	ELEC@plus acetabular insert 32/54-18
120375	ELEC@plus acetabular insert 36/43-18
120380	ELEC@plus acetabular insert 36/44-18
120390	ELEC@plus acetabular insert 36/46-18
120400	ELEC@plus acetabular insert 36/48-18
120410	ELEC@plus acetabular insert 36/50-18
120420	ELEC@plus acetabular insert 36/52-18
120430	ELEC@plus acetabular insert 36/54-18
120520	ELEC@plus acetabular insert 40/48-18
120530	ELEC@plus acetabular insert 40/50-18
120540	ELEC@plus acetabular insert 40/52-18
120550	ELEC@plus acetabular insert 40/54-18
120820	ELEC@plus acetabular insert 28/36-18±0
120825	ELEC@plus acetabular insert 28/40-18±0
120830	ELEC@plus acetabular insert 32/40-18±0
120840	ELEC@plus acetabular insert 32/44-18±0
120850	ELEC@plus acetabular insert 32/48-18±0
120860	ELEC@plus acetabular insert 32/52-18±0
120870	ELEC@plus acetabular insert 36/44-18±0
120880	ELEC@plus acetabular insert 36/48-18±0
120890	ELEC@plus acetabular insert 36/52-18±0
120900	ELEC@plus acetabular insert 36/54-18±0
120910	ELEC@plus acetabular insert 40/48-18±0
120920	ELEC@plus acetabular insert 40/52-18±0
120930	ELEC@plus acetabular insert 40/54-18±0
110460	ELEC@plus revision femoral head R28-16/18
110470	ELEC@plus revision femoral head R32-16/18
110480	ELEC@plus revision femoral head R36-16/18
110490	ELEC@plus revision femoral head R40-16/18
150000	Ti sleeve for ELEC@plus revision femoral head S (-3 mm) 16/18-12/14
150010	Ti sleeve for ELEC@plus revision femoral head M (±0 mm) 16/18-12/14
150020	Ti sleeve for ELEC@plus revision femoral head L (+4 mm) 16/18-12/14
150030	Ti sleeve for ELEC@plus revision femoral head XL (+7mm) 16/18-12/14
160000	ELEC@plus revision femoral head R 28-16/18 with Ti sleeve for ELEC@plus revision femoral head S (-3 mm) 16/18-12/14
160010	ELEC@plus revision femoral head R 28-16/18 with Ti sleeve for ELEC@plus revision femoral head M (±0 mm) 16/18-12/14

160020	ELEC@plus revision femoral head R 28-16/18 with Ti sleeve for ELEC@plus revision femoral head L (+4 mm) 16/18-12/14
160030	ELEC@plus revision femoral head R 28-16/18 with Ti sleeve for ELEC@plus revision femoral head XL (+7 mm) 16/18-12/14
160040	ELEC@plus revision femoral head R 32-16/18 with Ti sleeve for ELEC@plus revision femoral head S (-3 mm) 16/18-12/14
160050	ELEC@plus revision femoral head R 32-16/18 with Ti sleeve for ELEC@plus revision femoral head M (± 0 mm) 16/18-12/14
160060	ELEC@plus revision femoral head R 32-16/18 with Ti sleeve for ELEC@plus revision femoral head L (+4 mm) 16/18-12/14
160070	ELEC@plus revision femoral head R 32-16/18 with Ti sleeve for ELEC@plus revision femoral head XL (+7 mm) 16/18-12/14
160080	ELEC@plus revision femoral head R 36-16/18 with Ti sleeve for ELEC@plus revision femoral head S (-3 mm) 16/18-12/14
160090	ELEC@plus revision femoral head R 36-16/18 with Ti sleeve for ELEC@plus revision femoral head M (± 0 mm) 16/18-12/14
160100	ELEC@plus revision femoral head R 36-16/18 with Ti sleeve for ELEC@plus revision femoral head L (+4 mm) 16/18-12/14
160110	ELEC@plus revision femoral head R 36-16/18 with Ti sleeve for ELEC@plus revision femoral head XL (+7 mm) 16/18-12/14
160120	ELEC@plus revision femoral head R 40-16/18 with Ti sleeve for ELEC@plus revision femoral head S (-3 mm) 16/18-12/14
160130	ELEC@plus revision femoral head R 40-16/18 with Ti sleeve for ELEC@plus revision femoral head M (± 0 mm) 16/18-12/14
160140	ELEC@plus revision femoral head R 40-16/18 with Ti sleeve for ELEC@plus revision femoral head L (+4 mm) 16/18-12/14
160150	ELEC@plus revision femoral head R 40-16/18 with Ti sleeve for ELEC@plus revision femoral head XL (+7 mm) 16/18-12/14