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Nur zur elektronischen Verbreitung

EU Technical Documentation Assessment Certificate

We hereby certify that the company

ARTIQO GmbH
Hans-Böckler-Straße 57
59348 Lüdinghausen
Germany

has submitted a technical documentation in accordance with Annexes II and III of Regulation (EU) 2017/745, which meets the following requirements:

Annex IX – Chapter II (Assessment of the Technical Documentation)

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

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

Valid from	2024-12-10	Registration No.	D1423400029
Valid until	2029-12-09	Report No.	P22-01646-251261

Stuttgart, 2024-12-10

Notified Body

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

Devices:

ELEC® Plus Ceramic Femoral head 28 S
ELEC® Plus Ceramic Femoral head 28 M
ELEC® Plus Ceramic Femoral head 28 L
ELEC® Plus Ceramic Femoral head 32 S
ELEC® Plus Ceramic Femoral head 32 M
ELEC® Plus Ceramic Femoral head 32 L
ELEC® Plus Ceramic Femoral head 32 XL
ELEC® Plus Ceramic Femoral head 36 S
ELEC® Plus Ceramic Femoral head 36 M
ELEC® Plus Ceramic Femoral head 36 L
ELEC® Plus Ceramic Femoral head 36 XL
ELEC® Plus Revision Ceramic Femoral head 28 S
ELEC® Plus Revision Ceramic Femoral head 28 M
ELEC® Plus Revision Ceramic Femoral head 28 L
ELEC® Plus Revision Ceramic Femoral head 28 XL
ELEC® Plus Revision Ceramic Femoral head 32 S
ELEC® Plus Revision Ceramic Femoral head 32 M
ELEC® Plus Revision Ceramic Femoral head 32 L
ELEC® Plus Revision Ceramic Femoral head 32 XL
ELEC® Plus Revision Ceramic Femoral head 36 S
ELEC® Plus Revision Ceramic Femoral head 36 M
ELEC® Plus Revision Ceramic Femoral head 36 L
ELEC® Plus Revision Ceramic Femoral head 36 XL
BIOLOX® delta Ceramic Femoral head 28 S
BIOLOX® delta Ceramic Femoral head 28 M
BIOLOX® delta Ceramic Femoral head 28 L
BIOLOX® delta Ceramic Femoral head 32 S
BIOLOX® delta Ceramic Femoral head 32 M
BIOLOX® delta Ceramic Femoral head 32 L
BIOLOX® delta Ceramic Femoral head 32 XL
BIOLOX® delta Ceramic Femoral head 36 S
BIOLOX® delta Ceramic Femoral head 36 M
BIOLOX® delta Ceramic Femoral head 36 L
BIOLOX® delta Ceramic Femoral head 36 XL
BIOLOX® OPTION Ceramic Femoral head 28 S
BIOLOX® OPTION Ceramic Femoral head 28 M
BIOLOX® OPTION Ceramic Femoral head 28 L
BIOLOX® OPTION Ceramic Femoral head 28 XL
BIOLOX® OPTION Ceramic Femoral head 32 S
BIOLOX® OPTION Ceramic Femoral head 32 M
BIOLOX® OPTION Ceramic Femoral head 32 L
BIOLOX® OPTION Ceramic Femoral head 32 XL

BIOLOX® OPTION Ceramic Femoral head 36 S
BIOLOX® OPTION Ceramic Femoral head 36 M
BIOLOX® OPTION Ceramic Femoral head 36 L
BIOLOX® OPTION Ceramic Femoral head 36 XL

Intended purpose: The intended purpose of the medical device ceramic ball head according to ISO 6474-2 is as a femoral endoprosthesis (ball head) in combination with a suitable hip stem and a suitable acetabular endoprosthesis as an artificial hip joint in clinical use.

Risk class: III
Basic UDI-DI: 42511434031002CB

Notes:

For the placing on the market of the devices an EU Quality Management System Certificate according to Annex IX, Chapter I of Regulation (EU) 2017/745 on medical devices is also required.