EU Technical Documentation Assessment Certificate

We hereby certify that the company

ARTIQO GmbH
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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 2 pages. Details of the devices covered as well as further information and conditions are contained on the following pages.

Valid from	2024-07-05	Registration No.	D1423400027
Valid until	2028-12-19	Report No.	P22-00698-305344

Stuttgart, 2024-07-05

Notified Body

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

Devices:

A2® short stem cementless:
A2® stem size 0 Typ B, TPS-Bonit®
A2® stem size 1 Typ B, TPS-Bonit®
A2® stem size 2 Typ B, TPS-Bonit®
A2® stem size 3 Typ B, TPS-Bonit®
A2® stem size 4 Typ B, TPS-Bonit®
A2® stem size 5 Typ B, TPS-Bonit®
A2® stem size 6 Typ B, TPS-Bonit®
A2® stem size 7 Typ B, TPS-Bonit®
A2® stem size 8 Typ B, TPS-Bonit®
A2® stem size 9 Typ B, TPS-Bonit®
A2® stem size 10 Typ B, TPS-Bonit®
A2® stem size 11 Typ B, TPS-Bonit®
A2® stem size 0 Typ G, TPS-Bonit®
A2® stem size 1 Typ G, TPS-Bonit®
A2® stem size 2 Typ G, TPS-Bonit®
A2® stem size 3 Typ G, TPS-Bonit®
A2® stem size 4 Typ G, TPS-Bonit®
A2® stem size 5 Typ G, TPS-Bonit®
A2® stem size 6 Typ G, TPS-Bonit®
A2® stem size 7 Typ G, TPS-Bonit®
A2® stem size 8 Typ G, TPS-Bonit®
A2® stem size 9 Typ G, TPS-Bonit®
A2® stem size 10 Typ G, TPS-Bonit®
A2® stem size 11 Typ G, TPS-Bonit®
A2® stem size 0 Typ B, TPS
A2® stem size 1 Typ B, TPS
A2® stem size 2 Typ B, TPS
A2® stem size 3 Typ B, TPS
A2® stem size 4 Typ B, TPS
A2® stem size 5 Typ B, TPS
A2® stem size 6 Typ B, TPS
A2® stem size 7 Typ B, TPS
A2® stem size 8 Typ B, TPS
A2® stem size 9 Typ B, TPS
A2® stem size 10 Typ B, TPS
A2® stem size 11 Typ B, TPS
A2® stem size 0 Typ G, TPS
A2® stem size 1 Typ G, TPS
A2® stem size 2 Typ G, TPS
A2® stem size 3 Typ G, TPS
A2® stem size 4 Typ G, TPS
A2® stem size 5 Typ G, TPS

A2® stem size 6 Typ G, TPS
A2® stem size 7 Typ G, TPS
A2® stem size 8 Typ G, TPS
A2® stem size 9 Typ G, TPS
A2® stem size 10 Typ G, TPS
A2® stem size 11 Typ G, TPS

Intended purpose: The A2® stem (cementless and cemented) is used as a femoral endoprosthesis (hip stem) in combination with suitable ball heads and a compatible acetabular endoprosthesis to create an artificial hip joint.

Risk class: III
Basic UDI-DI: 42511434031001C9

A2® short stem cemented:
A2® stem size 2 Typ B, cemented
A2® stem size 3 Typ B, cemented
A2® stem size 4 Typ B, cemented
A2® stem size 5 Typ B, cemented
A2® stem size 6 Typ B, cemented
A2® stem size 7 Typ B, cemented
A2® stem size 8 Typ B, cemented
A2® stem size 9 Typ B, cemented
A2® stem size 10 Typ B, cemented

Intended purpose: The A2® stem (cementless and cemented) is used as a femoral endoprosthesis (hip stem) in combination with suitable ball heads and a compatible acetabular endoprosthesis to create an artificial hip joint.

Risk class: III
Basic UDI-DI: 42511434031003CD

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.

The certificate is based on the previous certificate

D1423400022 (2023-12-20)

with the following changes to D1423400022:
Supplemented by A2® stem size 10+11 Typ G, TPS-Bonit® and A2® stem size 10+11 Typ G, TPS