EU Technical Documentation Assessment Certificate

mdc medical device certification GmbH

Kriegerstr. 6, 70191 Stuttgart, Germany
Notified body (identification number 0483)

hereby certifies that the company (SRN: CH-MF-000020168)

Symbios Orthopédie S.A.

Avenue des Sciences 1
1400 Yverdon-les-Bains
Switzerland

EU Authorized Representative: Symbios France SAS, 14 Rue d'Arsonval, 69680 Chassieu, France
(AR-SRN: FR-AR-000017731)

has submitted a technical documentation for the devices listed on the following pages in accordance with Annexes II and III of Regulation (EU) 2017/745, which fulfils 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.

The certificate consists of 2 pages. Details of the devices affected by this certificate as well as further information and conditions are included on the following pages.

Valid from:	2023-12-19	Registration No.	D1487400005
Valid until:	2028-12-18	Evaluation Report No.	P22-00673-235027

Stuttgart, 2023-12-19

Head of Notified Body

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

Devices:

Product:
BIOLOX® Delta heads:
BIOLOX® Delta Head - Size Ø 28 mm / -3,5 mm
BIOLOX® Delta Head - Size Ø 28 mm / +0 mm
BIOLOX® Delta Head - Size Ø 28 mm / +3,5 mm
BIOLOX® Delta Head - Size Ø 32 mm / -4 mm
BIOLOX® Delta Head - Size Ø 32 mm / +0 mm
BIOLOX® Delta Head - Size Ø 32 mm / +4 mm
BIOLOX® Delta Head - Size Ø 32 mm / +7 mm
BIOLOX® Delta Head - Size Ø 36 mm / -4 mm
BIOLOX® Delta Head - Size Ø 36 mm / +0 mm
BIOLOX® Delta Head - Size Ø 36 mm / +4 mm
BIOLOX® Delta Head - Size Ø 36 mm / +8 mm

Intended purpose:
The BIOLOX® Delta Head is a single-use, sterile hip joint replacement femoral implant intended to be used in skeletally mature patients to relieve pain, restore hip function, and improve hip mobility by replacing the damaged hip joint in first intention and revision total hip arthroplasty.

Risk class: III
Basic-UDI-DI: 763001360ABC013002XXXXX5V

Product:
BIOLOX® Delta inserts:
BIOLOX® Delta Insert - 40-44 mm / Ø 28 mm
BIOLOX® Delta Insert - 46-50 mm / Ø 32 mm
BIOLOX® Delta Insert - 52-56 mm / Ø 36 mm
BIOLOX® Delta Insert - 58-64 mm / Ø 36 mm

Intended purpose:
The BIOLOX® Delta Insert is a single-use, sterile hip joint replacement acetabular implant intended to be used in skeletally mature patients to relieve pain, restore hip function, and improve hip mobility by replacing the damaged hip joint in primary total hip joint arthroplasty.

Risk class: III
Basic-UDI-DI: 763001360ADA00403XXXXXXNK

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.