

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 3 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.	D1487400007
Valid until:	2028-12-18	Evaluation Report No.	P22-01320-245223

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:

APRIL® Ceramic Acetabular Cups:

APRIL® Ceramic – Size 40mm
APRIL® Ceramic – Size 42mm
APRIL® Ceramic – Size 44mm
APRIL® Ceramic – Size 46mm
APRIL® Ceramic – Size 48mm
APRIL® Ceramic – Size 50mm
APRIL® Ceramic – Size 52mm
APRIL® Ceramic – Size 54mm
APRIL® Ceramic – Size 56mm
APRIL® Ceramic – Size 58mm
APRIL® Ceramic – Size 60mm
APRIL® Ceramic – Size 62mm
APRIL® Ceramic – Size 64mm

Intended purpose:

The APRIL® acetabular cups are single-use, sterile hip joint replacement implants 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 total hip arthroplasty.

Risk class: III

Basic-UDI-DI: 763001360ACA39101101001BR

Product:

APRIL® Poly Acetabular Cups:

APRIL® Poly – Size 40 mm
APRIL® Poly – Size 42mm
APRIL® Poly – Size 44mm
APRIL® Poly - Size 46mm
APRIL® Poly – Size 48mm
APRIL® Poly – Size 50mm
APRIL® Poly – Size 52mm
APRIL® Poly – Size 52mm Ext
APRIL® Poly – Size 54mm
APRIL® Poly – Size 56mm
APRIL® Poly – Size 58mm
APRIL® Poly – Size 60mm
APRIL® Poly – Size 62mm
APRIL® Poly – Size 64mm

Intended purpose:

The APRIL® acetabular cups are single-use, sterile hip joint replacement implants 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 total hip arthroplasty.

Risk class: III

Basic-UDI-DI: 763001360ACA39100101001B8

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.