ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

Product Service

EU Technical Documentation Assessment Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapter II
(Implantable Class IIb Devices and Class III Devices)

No. G70 039555 0224 Rev. 00

Manufacturer:

Edwards Lifesciences LLC
One Edwards Way
Irvine CA 92614
USA

SRN Manufacturer - US-MF-000007139

Authorized Representative:

Edwards Lifesciences GmbH
Parkring 30, 85748 Garching bei München, GERMANY

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has drawn up and presented a Technical Documentation according to Annex II and III of the Regulation (EU) 2017/745 on medical devices. Details on devices covered by the Technical Documentation are described on the following page(s).
The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The technical documentation assessment included an assessment of the clinical evaluation assessment.
The conformity assessment has been carried out according to Annex IX chapter II of this regulation with a positive result. Changes to the approved device, where such changes could affect the safety and performance of the device or the conditions prescribed for use of the device, shall require approval from the notified body TÜV SÜD Product Service GmbH.
In order to place the devices on the market with CE-marking, an EU Quality Management System Certificate pursuant to Annex IX chapters I and III is necessary in addition to this EU Technical Documentation Assessment Certificate. All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G70 039555 0224 Rev. 00

Report No.: 713302682

Valid from: 2025-04-11
Valid until: 2030-04-10

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2025-04-11

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

Product Service

EU Technical Documentation Assessment Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapter II
(Implantable Class IIb Devices and Class III Devices)

No. G70 039555 0224 Rev. 00

Classification:	Class III
Basic UDI-DI:	0690103D003SM3000TP
Intended Purpose:	The SAPIEN M3 transcatheter heart valve is intended to replace the mitral valve.
Device(s):	SAPIEN M3 Transcatheter Heart Valve Article Number: 9880TFX29M

Classification:	Class III
Basic UDI-DI:	0690103D003CM3000M7
Intended Purpose:	The Edwards Commander M delivery system is intended to facilitate the placement of the SAPIEN M3 valve.
Device(s):	Edwards Commander M Delivery System Article Number: 9880CM29

Classification:	Class III
Basic UDI-DI:	0690103D003EGS000SQ
Intended Purpose:	The Edwards 23F guide sheath is intended to provide access to the venous vasculature.
Device(s):	Edwards 23F Guide Sheath Article Number: 9880GS

Classification:	Class III
Basic UDI-DI:	0690103D003M3D000L6
Intended Purpose:	The SAPIEN M3 dock steerable catheter is intended to deliver the SAPIEN M3 dock to its intended location. The SAPIEN M3 dock, which is attached to the SAPIEN M3 dock steerable catheter, is intended to create a landing zone for the implantation of the SAPIEN M3 valve.
Device(s):	SAPIEN M3 Dock Steerable Catheter Article Number: 9880DDS

-

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

Product Service

EU Technical Documentation Assessment Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapter II
(Implantable Class IIb Devices and Class III Devices)

No. G70 039555 0224 Rev. 00

The validity of this certificate depends on conditions and/or is limited to the following: .

Revision History:

Rev.	Dated	Report	Description
00	2025-04-11	713302682	Initial issuance

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany