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 027625 0078 Rev. 01

Manufacturer:

TRB Chemedica AG
Otto-Lilienthal-Ring 26
85622 Feldkirchen/München
GERMANY

SRN Manufacturer - DE-MF-000006919

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 and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see:
www.tuvsud.com/ps-cert?q=cert:G70 027625 0078 Rev. 01

Report No.: 713295310

Preceding Certificate No.: G70 027625 0078 Rev. 00

Valid from: 2023-09-12
Valid until: 2027-06-28

Date of Initial Issuance: 2022-06-29

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2023-09-12

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

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No. G70 027625 0078 Rev. 01

Classification:	Class III
Device Group:	P900402 - RESORBABLE FILLING AND RECONSTRUCTION DEVICES
Basic UDI-DI:	4028694TENDONY8
Intended Purpose:	Viscoelastic solution for peritendinous or intrasheath injection for improvement of mobility and pain relief in tendon disorders
Device(s):	Ostenil Tendon 04028694000379 Ost Tendon 04028694000454 Hya-Ject Tendon 04028694001024

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

Revision History:

Rev.	Dated	Report	Description	
00	2022-06-29	713211260	-	
01	2023-09-12	713295310	Reduced: Device(s)/group of device(s) removed	Outphased products have been removed

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