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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 0077 Rev. 02

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 0077 Rev. 02

Report No.: 713271647

Preceding Certificate No.: G70 027625 0077 Rev. 01

Valid from: 2022-11-09
Valid until: 2027-02-06

Date of Initial Issuance: 2022-02-07

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2022-11-09

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
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No. G70 027625 0077 Rev. 02

Classification:	III
Device Group:	P900402 - RESORBABLE FILLING AND RECONSTRUCTION DEVICES
Basic UDI-DI:	4028694OSTENIL94
Intended Purpose:	Viscoelastic solution for injection into the joint cavity for improvement of mobility and pain relief in osteoarthritis Indications: Pain and restricted mobility of the knee and other big synovial joints like hip and shoulder.
Device(s):	Ostenil 04028694000034, 04028694000058, 04028694000041, 04028694000492, 04028694000935, 04028694000560, 04028694001093 Ost 04028694000430 Hya-Ject 04028694000638, 04028694000645, 04028694000652

Classification:	III
Device Group:	P900402 - RESORBABLE FILLING AND RECONSTRUCTION DEVICES
Basic UDI-DI:	4028694OSTMIN59
Intended Purpose:	Viscoelastic solution for injection into small joints for improvement of mobility and pain relief in osteoarthritis Indications: Pain and restricted mobility in degenerative and traumatic changes of small synovial joints, for example, the facet joints of the lumbar spine, the saddle joint of the thumb, the proximal joint of the big toe and the temporomandibular joint.
Device(s):	Ostenil Mini 04028694000119, 04028694001109 Ost Mini 04028694001123 Hya-Ject Mini 04028694000683

Classification:	III
Device Group:	P900402 - RESORBABLE FILLING AND RECONSTRUCTION DEVICES
Basic UDI-DI:	4028694OSTPLUSCR
Intended Purpose:	Viscoelastic solution for injection into the joint cavity for improvement of mobility and pain relief in osteoarthritis Indications: Pain and restricted mobility of the knee and other big synovial joints like hip and shoulder.
Device(s):	Ostenil Plus 04028694000294, 04028694001116, 04028694000942, 04028694000546 Ost Plus 04028694000447 Hya-Ject Plus 04028694000737

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

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No. G70 027625 0077 Rev. 02

Revision History:

Rev.	Dated	Report
00	2022-02-07	713202512
01	2022-04-29	713202512

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