



EU Declaration of Conformity

Manufacturer: TRB CHEMEDICA AG
Address: Otto-Lilienthal-Ring 26, D - 85622 Feldkirchen
SRN (Single Registration number): DE-MF-000006919

Product names: OSTENIL
OST
HYA-JECT

Basic UDI-DI: 4028694OSTENIL94

UDI-DI codes: OSTENIL 04028694000034, 04028694000058, 04028694000041,
04028694000492, 04028694001093, 04028694000935,
04028694000560
HYA-JECT 04028694000638, 04028694000645, 04028694000652
OST 04028694000430

Intended purpose: Viscoelastic solution for injection into the joint cavity for improvement of mobility and pain relief in osteoarthritis

Classification: Class III according to MDR, Annex VIII, rule 8 third indent

Conformity assessment route: MDR, Annex IX

We herewith declare under our sole responsibility that the above mentioned products comply with the requirements of Regulation (EU) 2017/745 concerning medical devices (MDR). All supporting documentation is retained under the premises of the manufacturer.

Notified Body: TÜV Süd Product Service GmbH (0123)
Ridlerstraße 65, D - 80339 München

EC Certificate (product): G70 027625 0077 Rev. 02, Annex IX (II), Regulation (EU) 2017/745
Valid until: 2027-02-06

EC Certificate (QMS): G12 027625 0079 Rev. 01, Annex IX (excl. chapter II),
Regulation (EU) 2017/745
Valid until: 2027-03-16

Place, Date: Feldkirchen, 22.10.2024

Signature:
Name:
Position:

- Carola Trümper -
PRRC

TRB CHEMEDICA AG

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Aufsichtsrat: Jens Horstkotte / Vorstand: Hans Kalkbrenner, Isaac Abad / HRB München: 114049 / USt-IdNr.: DE 182195789