



EU Declaration of Conformity

Manufacturer: TRB CHEMEDICA AG

Address: Otto-Lilienthal-Ring 26, D - 85622 Feldkirchen

SRN (Single Registration number): DE-MF-000006919

Product: OSTENIL TENDON
HYA-JECT TENDON
OST TENDON

Basic UDI-DI 4028694TENDONY8

UDI-DI codes OSTENIL TENDON 04028694000379
HYA-JECT TENDON 04028694001024
OST TENDON 04028694000454

Intended purpose: Viscoelastic solution for peritendinous or intrasheath injection for improvement of mobility and pain relief in tendon disorders

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: G70 027625 0078 Rev. 00,
Annex IX (II), Regulation (EU) 2017/745

Valid until: 2027-06-28

EC Certificate: G12 027625 0079 Rev.01,
Annex IX (excl. chapter II), Regulation (EU) 2017/745

Valid until: 2027-03-16

Place, Date: Feldkirchen, 27.07.2023

Signature:

Name:

- Carola Trümper -

Position:

PRRC

TRB CHEMEDICA AG

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