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: Valid until:	G70 027625 0078 Rev. 01, Annex IX (II), Regulation (EU) 2017/745 2027-06-28
EC Certificate: Valid until:	G12 027625 0079 Rev.01, Annex IX (excl. chapter II), Regulation (EU) 2017/745 2027-03-16

Place, Date:	Feldkirchen, 22.09.2023
Signature:	Carola Trümper
Name:	- Carola Trümper -
Position:	PRRC

TRB CHEMEDICA AG
Otto-Lilienthal-Ring 26 / 85622 Feldkirchen b. München, Deutschland
Tel +49 (0)89 46 14 83-0 / Fax +49 (0)89 46 14 83-85 / info@trbchemedica.de / www.trbchemedica.de
Aufsichtsrat: Jens Horstkotte / Vorstand: Hans Kalkbrenner, Isaac Abad / HRB München: 114049 / USt-IdNr.: DE 182195789