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, 21.07.2022

Signature:

Name: - C a r o l a T r ü m p e r -

Position: PRRC