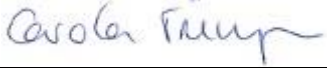
EU Declaration of Conformity

Manufacturer:	TRB CHEMEDICA AG
Address:	Otto-Lilienthal-Ring 26, D - 85622 Feldkirchen
SRN (Single Registration number):	DE-MF-000006919
Product names:	OSTENIL MINI OST MINI HYA-JECT MINI
Basic UDI-DI	4028694OSTMIN59
UDI-DI codes:	OSTENIL MINI 04028694000119, 04028694001109, 04028694000522 OST MINI 04028694001123 HYA-JECT MINI 04028694000683
Intended purpose:	Viscoelastic solution for injection into small joints 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): Valid until:	G70 027625 0077 Rev. 03, Annex IX (II), Regulation (EU) 2017/745 2027-02-06
EC Certificate (QMS): Valid until:	G12 027625 0079 Rev. 01, Annex IX (excl. chapter II), Regulation (EU) 2017/745 2027-03-16
Place, Date:	Feldkirchen, 10.11.2025
Signature:	
Name:	- C a r o l a T r ü m p e r -
Position:	PRRC

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