EU Declaration of Conformity

Manufacturer:	TRB CHEMEDICA AG	
Address: SRN (Single Registration number):	Otto-Lilienthal-Ring 26, D - 85622 Feldkirchen DE-MF-000006919	
Product names:	OSTENIL OST HYA-JECT	
Basic UDI-DI:	4028694OSTENIL94	
UDI-DI codes:	OSTENIL	04028694000034, 04028694000058, 04028694000041, 04028694000492, 04028694001093, 04028694000935, 04028694000560, 04028694001505, 04028694000515
	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): 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: - Carola Trümper -

Position: PRRC

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