



## 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  
OST  
HYA-JECT

Basic UDI-DI: 4028694OSTENIL94

UDI-DI codes: OSTENIL 04028694000034, 04028694000058, 04028694000041,  
04028694000492, 04028694001093, 04028694000935,  
04028694000560  
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): G70 027625 0077 Rev. 02, Annex IX (II), Regulation (EU) 2017/745  
Valid until: 2027-02-06

EC Certificate (QMS): 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:  
Position:

- Carola Trümper -  
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](http://www.trbchemedica.de)

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