



## 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 PLUS  
HYA-JECT PLUS  
MAXIOSTENIL PLUS  
OST PLUS  
OSTEONIL PLUS  
Basic UDI-DI: 4028694OSTPLUSCR  
UDI-DI codes: OSTENIL PLUS 04028694000294, 04028694001116,  
04028694000485, 04028694000942,  
04028694000744, 04028694000546,  
04028694000591, 07703546704038  
HYA-JECT PLUS 04028694000737  
OST PLUS 04028694000447  
MAXIOSTENIL PLUS 04028694000614  
OSTEONIL PLUS 07896281100590  
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. 01, Annex IX (II), Regulation (EU) 2017/745  
Valid until: 2027-04-10  
EC Certificate (QMS): G12 027625 0079 Rev.00, Annex IX (excl. chapter II),  
Regulation (EU) 2017/745  
Valid until: 2027-03-16

Place, Date: Feldkirchen, 05.05.2022

Signature:  
Name:  
Position:

- Carola Trümper -  
PRRC

### TRB CHEMEDICA AG

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