

### ***Declaration of Conformity***

Manufacturer: TRB CHEMEDICA AG

Address: Richard-Reitzner-Allee 1, D - 85540 Haar

Product: OSTENIL PLUS  
HYA-JECT PLUS  
MAXIOSTENIL PLUS  
OST PLUS  
OSTEONIL PLUS

Intended use: Viscoelastic solution for injection into the joint cavity

Classification: Class III according to MDD, Annex IX, rule 7 sentence 4

Conformity assessment route: MDD, Annex II.3 and II.4

**We herewith declare under our sole responsibility that the above mentioned product complies with the requirements of Annex I of the Council Directive 93/42/EEC concerning medical devices (MDD). All supporting documentation is retained under the premises of the manufacturer.**

Standards applied: For the harmonized standards applicable to this product please refer to the effective manufacturer's List of Norms and Standards

Notified Body: TÜV Süd Product Service GmbH (0123)  
Ridlerstraße 65, D - 80339 München

EC Certificate: G1 16 11 27625 066, Annex II.3, MDD 93/42/EEC  
Valid until: January 15<sup>th</sup>, 2022

EC Certificate: G7 12 02 27625 058, Annex II.4, MDD 93/42/EEC  
Valid until: March 17<sup>th</sup>, 2017

Date, when CE mark was affixed: 20.02.2009

Launch Date: 23.02.2009

Place, Date: Haar / München, 16.01.2017

Signature:

Name:

Position:

  
- Hans Kalkbrenner -  
Management Representative