

## IZJAVA O SKLADNOSTI *DECLARATION OF CONFORMITY*

Podjetje/Company:

**INTERDENT® d.o.o.**

Naslov/Address:

**Opekarniška cesta 26, SI - 3000 CELJE**

Na lastno odgovornost izjavljamo, da sledeči proizvodi, razreda IIa (pravilo 5)  
*We herewith declare on our responsibility that the following Class IIa Products (rule 5)*

### **CAD/CAM PMMA plošče** ***CAD/CAM PMMA discs***

CC DISK PMMA, barva/*colours*: A1, A2, A3, B1, B2, B3, BL1, BL2, BL3, E1, E2;  
debelina/*thickness*: 12mm, 14mm, 15mm, 16mm, 18mm, 20mm, 25mm,  
CC DISK PMMA 3-layers barva/*colours*: A3; debelina/*thickness*: 15mm, 18mm,  
CC DISK PMMA barva/*colour*: roza/*pink*, debelina/*thickness*: 25mm, 27mm, 30mm

ustrezajo bistvenim zahtevam Direktive o medicinskih pripomočkih 93/42/EGS.  
*comply with essential requirements of the Medical Devices Directive 93/42 EEC.*

Postopek ugotavljanja skladnosti: Dodatek II (brez točke 4) Direktive o medicinskih pripomočkih 93/42/EGS, datum izdaje: 19. 03. 2014, številka registracije: HD 60093140 0001, veljavnost certifikata: 20. 02. 2019  
*Conformity assessment procedure: Annex II (without point 4) of Medical Device Directive 93/42/EEC, date of issue: 19<sup>th</sup> March, 2014, registration No: HD 60093140 0001, certificate validity: 20<sup>th</sup> Feb. 2019*

Priglašeni organ za ugotavljanje skladnosti / *Notified body*:

TÜV Rheniland LGA Products Gmbh, Tillystrasse 2, D – 90431 Nürnberg – številka / *number* **0197**

#### HARMONIZIRANI STANDARDI / *HARMONISED STANDARDS*:

ISO 13485:2012: Medicinski pripomočki – Sistem vodenja kakovosti- Zahteve za zakonodajne namene / *Medical devices – Quality management systems – Requirements for regulatory purposes*

EN ISO 14971:2012 Medicinski pripomočki-Uporaba obvladovanja tveganja pri medicinskih pripomočkih / *Medical devices - Application of risk management to medical devices*

EN ISO 10993-1:2009: Biološko vrednotenje medicinskih pripomočkov – 1.del: Ocena in preskusi / *Biological evaluation of medical devices – Part 1: Evaluation and testing*

EN ISO 10993-5:2009: Biološko vrednotenje medicinskih pripomočkov – 5 del: Preskusi za ugotavljanje citotoksičnosti in vitro / *Biological Evaluation of Medical Devices- Part 5: 2009 Testing of cytotoxicity: In vitro methods,*

EN 62366:2008: Medicinske naprave – Uporaba inženirstva uporabljivosti pri medicinskih napravah / *Medical devices – Application of usability engineering to medical devices*

EN ISO 15223-1:2012: Medicinski pripomočki – Simboli za označevanje medicinskih pripomočkov, označevanje in podatki, ki jih mora podati dobavitelj- 1.del: Splošne zahteve / *Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – part 1: general requirements*

EN ISO 10477 Zobozdravstvo – Polimerni materiali za krone in mostičke / *Dentistry – Polymer based crown and bridge materials*

EN ISO 20795-1 Zobozdravstvo – Osnovni polimeri – 1. Del: Osnovni polimeri za proteze / *Dentistry- Base polymers – Part 1: denture base polymers*

ISO 178 Plastika – Določanje lastnosti plastičnosti / *Plastic – Determination of plastic properties*

EN ISO 7405:2008 *Zobozdravstvo – Ocena biokompatibilnosti medicinskih pripomočkov v zobozdravstvu* / *Dentistry – Evaluation of biocompatibility of medical devices used in dentistry*

EN ISO 10.993 Biološko vrednotenje medicinskih pripomočkov – 10.del: 2004 Preskuso draženja in preobčutljivosti kože / *Biological evaluation of medical devices – Part 10:2004 Test for irritation and skin sensitization.*

EN ISO 9001:2008- Sistem vodenja kakovosti – zahteve / *Quality management system - Requirements*

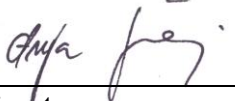
Veljavnost izjave o skladnosti je vezana na spremembo medicinskega pripomočka ali na veljavnost certifikata priglšenega organa. / *The validity of declaration of conformity is linked to a change in medical device or on validity of certificate issued by notified body*

Celje, 16. 01. 2016

**Place, Date**

Anja Šraj, univ.dpl.chem.

**Responsible person for MD and technical files**

  
**Signature:**

**Verzija/Version: 1**