

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 8)
We herewith declare on our responsibility that the following Class IIa Products (rule 8)

CAD/CAM plošče ***CAD/CAM discs***

DISK BOND NF (REF 1900 – 8 mm, REF 1901 – 10 mm, REF 1902 – 12 mm, REF 1903 – 13,5 mm, REF 1904 – 15 mm, REF 1905 – 18 mm)

UMDNS Št / UMDNS No :10-077

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: 19th March, 2014, registration No: HD 60093140 0001, certificate validity: 20th 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 ISO 22674:2006: Zobozdravstvo – kovinski materiali za stalne in zamenljive zobne obnove in orodja / *Metallic materials for fixed and removable restorations and appliances*

EN ISO 9693-1:2012 Zobozdravstvo – preskušanje združljivosti – 1. Del: Kovinsko-keramični sistemi / *Dentistry – compatibility testing – Part 1: Metal-ceramic systems*

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

EN ISO 10271:2011 Zobozdravstvo - Preskusne metode ugotavljanja korozije za kovinske materiale / *Dentistry – Corrosion test methods for metallic materials*


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*

Celje, 08.04. 2014

Place, Date

Anja Šraj, univ.dpl.chem.

Responsible person for MD and technical files



Signature: