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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

CC DISK Zr premer / *diameter*: 98 mm, barva / *colour*: opačna / *opaque*, debelina / *thickness*: 10 mm, 12 mm, 14 mm, 16 mm, 18 mm, 20 mm, 22 mm, 25 mm
CC DISK Zr premer / *diameter*: 98 mm, barva opačna / *colour opaque*: A1, A2, A3, debelina / *thickness*: 10 mm, 12 mm, 14 mm, 16 mm, 18 mm, 20 mm, 22 mm, 25 mm
CC DISK Zr premer / *diameter*: 98 mm, barva / *colour*: visoka translucenca / *high translucent*, debelina / *thickness*: 10 mm, 12 mm, 14 mm, 16 mm, 18 mm, 20 mm, 22 mm, 25 mm
CC DISK Zr premer / *diameter*: 98 mm, barva visoko translucentna / *colour high translucent*: A1, A2, A3, B1, B2, C2, debelina / *thickness*: 10 mm, 12 mm, 14 mm, 16 mm, 18 mm, 20 mm, 25 mm
CC DISK Zr premer / *diameter*: 98 mm, večbarvni / *multicolour*: A2, A3, debelina / *thickness*: 14 mm, 18 mm, 22 mm
CC DISK Zr Smile, premer / *diameter*: 98 mm, barva / *colour*: opačna / *opaque*, debelina / *thickness*: 12 mm, 14 mm, 16 mm, 18 mm, 20 mm, 25 mm
CC DISK Zr Smile, premer / *diameter*: 98 mm, barva opačna / *colour opaque*: A1, A2, A3.5, debelina / *thickness*: 14 mm, 18 mm

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:*

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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 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 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*
EN ISO 6872:2008 – Zobozdravstvo – keramični materiali / *Dentistry – Ceramic materials*

Veljavnost izjave o skladnosti je vezana na spremembo medicinskega pripomočka ali na veljavnost certifikata priglašenega 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, 12. 01. 2016	Anja Šraj, univ.dpl.chem.	
Place, Date	**Responsible person for MD and technical files**	**Signature:**

Verzija/Version: 1