Sl – 3000 CELJE – Opekarniška cesta 26
Tel.: +386 (0) 3 425-62-00 Fax: +386 (0) 3 425-62-10
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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 Ti5 diameter: 98,5 mm, thickness: REF 1907 – 8 mm, REF 1908 – 10 mm, REF 1909 – 12 mm, REF 1910 – 13,5 mm, REF 1911 – 15 mm, REF 1912 – 18 mm, REF 1921 – 20 mm, REF 1922 – 22 mm, REF 1923 – 25 mm
CC DISK Ti2 diameter: 98,5 mm, thickness: REF 1915 – 8 mm, REF 1916 – 10 mm, REF 1917 – 12 mm, REF 1918 – 13,5 mm, REF 1919 – 15 mm, REF 1920 – 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*

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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 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*
ASTM F67-00: Standardna specifikacija za nelegiran Titan, za kirurške vsadke / *Standard Specification for Unalloyed Titanium, for Surgical Implant Application*
ASTM F136-08: Standardna specifikacija za legiran Titan-6 Aluminije-4 Vanadij za kirurške vsadke / *Standard Specification for Wrought Titanium-6 Aluminium-4 Vanadium Alloy for Surgical Implant Applications*
ISO 5832-2:2015: Kirurški vsadki – Kovinski materiali – Del 2: Nelegiran titan / *Implants for surgery -- Metallic materials -- Part 2: Unalloyed titanium*
ISO 5832-3:2012 Kirurški vsadki- Kovinski materiali – Del 3: Legiran Titan-6 Aluminij-4 Vanadij / *Implants for surgery -- Metallic materials -- Part 3: Wrought titanium 6-aluminium 4-vanadium alloy*
Standard Specification for Unalloyed Titanium, for Surgical Implant Application
EN ISO 9001:2008- Sistem vodenja kakovosti – zahteve / *Quality management system – Requirements*
EN ISO 7405:2008 *Zobozdravstvo – Ocena biokompatibilnosti medicinskih pripomočkov v zobozdravstvu /* Dentistry – Evaluation of biocompatibility of medical devices used in dentistry

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Celje, 14.04.2016 — **Place, Date**

Anja Šraj, univ.dpl.chem. — **Responsible person for MD and technical files**

Signature:

Verzija/Version: 1