

IZJAVA EU O SKLADNOSTI EU DECLARATION OF CONFORMITY

Podjetje/ Company: **INTERDENT® d.o.o.**
Naslov/ Address: **Opekarniška cesta 26, SI - 3000 CELJE**
SRN: **SI-MF-000004584**

Izjavljamo, da smo kot proizvajalec izključno odgovorni za izdajo izjave EU o skladnosti. /
We declare, that as a manufacturer, we are solely responsible for issuing the EU declaration of conformity.

Sledeči proizvodi, razvrščeni v razred IIa (pravilo 5) po prilogi VIII MDR,
Following Class IIa Products (rule 5) according to Annex VIII of the MDR,

GENERIČNO IME / GENERIC NAME	DENTALNE ZLITINE NEPLEMENITE / DENTAL ALLOYS NONPRECIOUS
TRGOVSKO IME / TRADE NAME	I-MG, I-MG FH, I-MG EKO, I-MG HE
GMDN	35857
EMDN	Q010601
OSNOVNI UDI-DI / BASIC UDI-DI	++D058DENTALALLOYS2AP84

ustrezajo splošnim zahtevam glede varnosti in učinkovitosti Uredbe o medicinskih pripomočkih (EU) 2017/745 (MDR).

comply with general safety and performance requirements of the Medical Devices Regulation (EU) 2017/745 (MDR).

Postopek ugotavljanja skladnosti: Dodatek IX, Poglavlje I Uredbe o medicinskih pripomočkih (EU) 2017/745, datum izdaje: 10.05.2023, številka registracije: HZ1076832-1, veljavnost certifikata: 09.05.2028 *Conformity assessment procedure: Annex IX, Chapter I of Medical Devices Regulation (EU) 2017/745, date of issue: 10.05.2023, registration No: HZ1076832-1, certificate validity: 09.05.2028*

Priglašeni organ za ugotavljanje skladnosti / *Notified body.*

TÜV Rheinland LGA Products GmbH, Tillystrasse 2, D – 90431 Nürnberg – številka / *number* **0197**

HARMONIZIRANI IN OSTALI STANDARDI / *HARMONISED AND OTHER STANDARDS:*

EN ISO 13485:2016+A11:2021 Medicinski pripomočki – Sistem vodenja kakovosti – Zahteve za zakonodajne namene / *Medical devices – Quality management systems – Requirements for regulatory purposes*

EN ISO 14971:2019/A11:2021 Medicinski pripomočki-Uporaba obvladovanja tveganja pri medicinskih pripomočkih / *Medical devices - Application of risk management to medical devices*

EN ISO 15223-1:2021 Medicinski pripomočki – Simboli za označevanje medicinskih pripomočkov - 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 10993-1:2020 Biološko vrednotenje medicinskih pripomočkov – 1. del: Ocena in preskusi znotraj ocene tveganja / *Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process*

EN ISO 10993-3:2014 Biološko vrednotenje medicinskih pripomočkov – 3. del: Preskusi za genotoksičnost, rakotvornost in reproduktivno toksičnost / *Biological evaluation of medical devices – Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity*

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

EN ISO 10993-6:2009 Biološko vrednotenje medicinskih pripomočkov – 6. del: Preskusi za lokalne učinke po vstavitvi vsadkov. / *Biological evaluation of medical devices – Part 6: Tests for local effects after implantation*

EN ISO 10993-9:2021 Biološko ovrednotenje medicinskih pripomočkov - 9. del: Okvirni sistem za prepoznavanje in ugotavljanje količine morebitnih razgradnih produktov / *Biological evaluation of medical devices - Part 9: Framework for identification and quantification of potential degradation products*

EN ISO 10993-10:2013 Biološko vrednotenje medicinskih pripomočkov – 10. del: Preskusi za draženje in preobčutljivost kože. / *Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization*

EN ISO 10993-11:2018 Biološko vrednotenje medicinskih pripomočkov – 11. del: Preskusi za sistemsko toksičnost / *Biological evaluation of medical devices – Part 11: Tests for systemic toxicity*

EN ISO 10993-12:2021 Biološko ovrednotenje medicinskih pripomočkov - 12. del: Priprava vzorcev in referenčni materiali / *Biological evaluation of medical devices - Part 12: Sample preparation and reference materials*

EN ISO 10993-15:2009 Biološko vrednotenje medicinskih pripomočkov – 15. del: Identifikacija in kvantifikacija proizvodov razgradnje kovin in zlitin / *Biological evaluation of medical devices – Part 15: Identification and quantification of degradation products from metals and alloys*

EN ISO 10993-17:2009 Biološko ovrednotenje medicinskih pripomočkov - 17. del: Postavitev dopustnih mej za izlužene snovi / *Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances*

EN ISO 10993-18:2020 Biološko vrednotenje medicinskih pripomočkov – 18. del: Kemijska opredelitev materialov / *Biological evaluation of medical devices – Part 18: Chemical characterization of materials*

EN ISO 7405:2018 Zobozdravstvo – Ocena biokompatibilnosti medicinskih pripomočkov v zobozdravstvu / *Dentistry – Evaluation of biocompatibility of medical devices used in dentistry*

EN 62366-1:2015/A1:2020 Medicinski pripomočki – Uporaba inženiringa uporabnosti medicinskih pripomočkov / *Medical devices – Application of usability engineering to medical devices*

EN 1641:2009 Zobozdravstvo. Medicinski pripomočki za zobozdravstvo. Materiali / *Dentistry. Medical devices for dentistry. Materials.*

CEN ISO/TR 20416:2020 Medicinski pripomočki - Nadzor proizvajalcev po dajanju v promet / *Medicinski pripomočki - Nadzor proizvajalcev po dajanju v promet*

EN ISO 20417:2021 Informacije proizvajalca za medicinske pripomočke / *Information supplied by the manufacturer of medical devices*

EN ISO 22674:2022 Zobozdravstvo – kovinski materiali za stalne in zamenljive zobne obnove in orodja. / *Metallic materials for fixed and removable restorations and appliances*

EN ISO 10271:2020 Zobozdravstvo – Preskusne metode ugotavljanja korozije za kovinske material / *Dentistry – Corrosion test methods for metallic materials*

ISO/TS 10993-19:2020 Biological evaluation of medical devices – Part 19: Physico-chemical, morphological and topographical characterization of materials

EN ISO 10993-23:2021 Biološko ovrednotenje medicinskih pripomočkov - 23. del: Preskusi draženja / *Biological evaluation of medical devices – Part 23: Tests for irritation*

ISO/TS 21726:2019 Biološko vrednotenje medicinskih pripomočkov – Uporaba praga toksikološke zaskrbljenosti (TTC) za oceno biokompatibilnosti sestavin medicinskih pripomočkov / *Biological evaluation of medical devices – Application of the threshold of toxicological concern (TTC) for assessing biocompatibility of medical device constituents*

EN ISO 9333:2022 Zobozdravstvo – materiali za spajkanje / *Dentistry – Brazing materials*

EN ISO 9001:2015 Sistem vodenja kakovosti – zahteve / *Quality management system – requirements*

CR 13695-1:2000 Embalaža - Zahteve za merjenje in overjanje štirih težkih kovin in drugih nevarnih snovi v embalaži ter njihov izpust v okolje - 1. del: Zahteve za merjenje in overjanje štirih težkih kovin in drugih nevarnih snovi v embalaži / *Packaging – Requirements for measuring and verifying the four heavy metals and other dangerous substances present in packaging and their release into the*

environment – Part 1: Requirements for measuring and verifying the four heavy metals present in packaging

EN ISO 4180:2019 Embalaža - Celovita, napolnjena transportna embalaža - Splošna pravila za pripravo programov preskušanja primernosti za uporabo / *Packaging – Complete, filled transport packages – General rules for the compilation of performance test schedules*

ANSI/HIBC 2.6 standard 2016: Standard označevanja dobaviteljev zdravstvene industrije za varnost pacientov in edinstveno identifikacijo naprave (UDI) / *The health industry supplier labeling standard for patient safety & unique device identification (UDI)*

Veljavnost izjave o skladnosti je vezana na spremembo medicinskega pripomočka ali na veljavnost certifikata priglašene 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, 11.05.2023

Place, Date

Anja Mavrič, B.Sc.

Responsible person for technical files



Signature:

Verzija / Version: MDR 1

ANNEX TO DECLARATION OF CONFORMITY VERSION MDR 1 – ALL REF COVERED:

REF	TYPE/VARIANTS
1706	I MG 1000 g
1707	I MG 500 g
1708	I MG 250 g
1709	I-MG FH 1000 g
1710	I-MG FH 500 g
1711	I-MG FH 250 g
1716	I-GW 1000g
1717	I-GW 500g
1718	I-GW 250g
1719	I-MG EKO 1000g
1720	I-MG EKO 500g
1721	I-MG EKO 250g
1725	I-MG HE 1000g
1726	I-MG HE 500g

