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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*	**DENTALNA KOVANA ZLITINA / *DENTAL WROUGHT ALLOY***
TRGOVSKO IME / *TRADE NAME*	**ŽICA ZA ZAPONE / *CLASP WIRE*** **PODJEZIČNI LOKI / *LOWER LINGUAL BARS***
GMDN	38608
EMDN	Q010601
OSNOVNI UDI-DI / *BASIC UDI-DI*	++D058WIREBARS2AZ2

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, Poglavje 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*
CEN ISO/TR 24971:2020 Medicinski pripomočki - Navodilo za uporabo ISO 14971 / *Medical devices – Guidance on the application of ISO 14971*
EN ISO 15223-1:2021/A1:2025 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 10993-1:2026 Biološko ovrednotenje medicinskih pripomočkov - 1. del: Zahteve in splošna načela za oceno biološke varnosti znotraj procesa obvladovanja tveganja / Biological Evaluation of Medical Devices- Part 1: Requirements and general principles for the evaluation of biological safety within a risk management process

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EN ISO 10993-5:2009/A11:2025 Biološko vrednotenje medicinskih pripomočkov – 5. del: Preskusi zaugotavljanje citotoksičnosti in vitro / Biological Evaluation of Medical Devices- Part 5: Tests for in vitro cytotoxicity
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 10993-10:2023 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 10993-12:2021/A1:2025 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 10993-15:2023 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 10993-17:2023 /A1:2025 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/A1:2023 Biološko vrednotenje medicinskih pripomočkov – 18. del: Kemijska opredelitev materialov / *Biological evaluation of medical devices – Part 18: Chemical characterization of materials*
EN ISO 7405:2025 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*
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/A1:2025 Biološko ovrednotenje medicinskih pripomočkov - 23. del: Preskusi draženja / Biological evaluation of medical devices – Part 23: Tests for irritation
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 Zobozdravstvc – Preskusne metode ugotavljanja korozije za kovinske material */ Dentistry – Corrosion test methods for metallic materials*
EN ISO 6931-1:2020 Nerjavno jeklo za vzmeti - 1. del: Žica */ Stainless steels for springs - Part 1: Wire*
EN 10088-3:2014 Nerjavna jekla - 3. del: Tehnični dobavni pogoji za polizdelke, drogove, palice, žico, profile in svetle izdelke iz korozijsko odpornih jekel za splošno uporabo / *Stainless steel – Part 3: Technical delivery conditions for semi-finished products, bars, rods, wire, sections and bright products of corrosion resisting steel for general purposes*
EN ISO 9001:2015/A1:2024 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*

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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 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, 10.04.2026 — **Place, Date**

Anja Mavrič, B.Sc. — **Responsible person for regulatory compliance (MDR, Article 15 (3): (b) & (c))**

Signature:

Verzija / *Version*: MDR 1

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

CATALOGUE (REF) NUMBER	UDI-DI	DESCRIPTION
REF 306	+D05800000000003060	ŽICA ZA ZAPONE / CLASP WIRE 0,6 mm, 3 m
REF 307	+D05800000000003070	ŽICA ZA ZAPONE / CLASP WIRE 0,7 mm, 3 m
REF 308	+D05800000000003080	ŽICA ZA ZAPONE / CLASP WIRE 0,8 mm, 3 m
REF 309	+D05800000000003090	ŽICA ZA ZAPONE / CLASP WIRE 0,9 mm, 3 m
REF 310	+D05800000000003100	ŽICA ZA ZAPONE / CLASP WIRE 1,0 mm, 3 m
REF 311	+D05800000000003110	ŽICA ZA ZAPONE / CLASP WIRE 1,1 mm, 3 m
REF 312	+D05800000000003120	ŽICA ZA ZAPONE / CLASP WIRE 1,2 mm, 3 m
REF 306-40	+D05800000000306400	ŽICA ZA ZAPONE / CLASP WIRE 0,6 mm, 40 m
REF 307-30	+D05800000000307300	ŽICA ZA ZAPONE / CLASP WIRE 0,7 mm, 30 m
REF 308-20	+D05800000000308200	ŽICA ZA ZAPONE / CLASP WIRE 0,8 mm, 20 m
REF 309-10	+D05800000000309100	ŽICA ZA ZAPONE / CLASP WIRE 0,9 mm, 10 m
REF 310-10	+D05800000000310100	ŽICA ZA ZAPONE / CLASP WIRE 1,0 mm, 10 m

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REF 311-10	+D05800000000311100	ŽICA ZA ZAPONE / CLASP WIRE 1,1 mm, 10 m
REF 312-10	+D05800000000312100	ŽICA ZA ZAPONE / CLASP WIRE 1,2 mm, 10 m
REF 324	+D05800000000003240	PODJEZIČNI LOKI / LOWER LINGUAL BARS 7 cm, 10 kos
REF 325	+D05800000000003250	PODJEZIČNI LOKI / LOWER LINGUAL BARS 8 cm, 10 kos
REF 326	+D05800000000003260	PODJEZIČNI LOKI / LOWER LINGUAL BARS 9 cm, 10 kos