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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 8) po prilogi VIII MDR,
Following Class IIa Products (rule 8) according to Annex VIII of the MDR,

GENERIČNO IME / *GENERIC NAME*	**CAD/CAM DISKI Ti / *CAD/CAM DISCS Ti***
TRGOVSKO IME / *TRADE NAME*	**CC DISK Ti5**
GMDN	62817
EMDN	Q010601
OSNOVNI UDI-DI / *BASIC UDI-DI*	++D058CCDISKTI52AV8

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: 25.11.2025, 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:* 25.11.2025*, 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*

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Medical Devices- Part 1: Requirements and general principles for the evaluation of biological safety 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/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 10993-6:2016 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 10993-10:2023 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 10993-11:2018 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/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 7405:2018 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 9693:2019 Zobozdravstvo – preskušanje združljivosti – 1. Del: Kovinsko-keramični sistemi */ Dentistry – compatibility testing – Part 1: Metal-ceramic systems*
ASTM F136-13 Standardna specifikacija za titan in titan-6 aluminij-4 vanadijevo zlitino za uporabo v kirurških vsadkih */ Standard Specification for Titanium and Titanium-6 Aluminum-4 Vanadium Alloy for Surgical Implant Application*
EN ISO 5832-3:2021 Vsadki (implantati) za kirurgijo - Kovinski materiali - 3. del: Titanova 6-aluminijeva 4-vanadijeva zlitina */ Implants for surgery -- Metallic materials -- Part 3: Wrought titanium 6-aluminium 4-vanadium alloy*

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EN ISO 10271:2020 Zobozdravstvc – Preskusne metode ugotavljanja korozije za kovinske materiale / *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/A1:2025 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 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 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, 04.06.2026	Anja Mavrič, B.Sc.	
Place, Date	**Responsible person for regulatory compliance (MDR, Article 15 (3): (b) & (c))**	**Signature:**

Verzija / *Version*: MDR 2

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ANNEX TO DECLARATION OF CONFORMITY VERSION MDR 2 – ALL REF COVERED:

CATALOGUE (REF) NUMBER	UDI-DI	DESCRIPTION
1908	+D058000000000019080	CC DISK Ti5 10 mm
1909	+D058000000000019090	CC DISK Ti5 12 mm
1910	+D058000000000019100	CC DISK Ti5 13,5 mm
1911	+D058000000000019110	CC DISK Ti 15 mm
1912	+D058000000000019120	CC DISK Ti5 18 mm
1913	+D058000000000019130	CC DISK Ti5, 13.5mm
1921	+D058000000000019210	CC DISK Ti5 20 mm
1922	+D058000000000019220	CC DISK Ti5 22 mm
1923	+D058000000000019230	CC DISK Ti5 25 mm
1890	+D058000000000018900	CC DISK Ti5, 95x10 mm
1891	+D058000000000018910	CC DISK Ti5, 95x12 mm
1892	+D058000000000018920	CC DISK Ti5, 95x13,5 mm
1893	+D058000000000018930	CC DISK Ti5, 95x15 mm
1894	+D058000000000018940	CC DISK Ti5, 95x18 mm
1895	+D058000000000018950	CC DISK Ti5, 95x20 mm
1896	+D058000000000018960	CC DISK Ti5, 95x22 mm