INTERDENT® d.o.o.
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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*	**SESALKE ZA SLINO / *SALIVA EJECTORS***
TRGOVSKO IME / *TRADE NAME*	**SESALKE ZA SLINO / *SALIVA EJECTORS***
GMDN	37434
EMDN	Q019001
OSNOVNI UDI-DI / *BASIC UDI-DI*	++D058SALIVAEJECTORS2AUU

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, poglavje 2 in 3 Uredbe o medicinskih pripomočkih (EU) 2017/745, datum izdaje: 06.11.2024, številka registracije: HZ 1076832-1, veljavnost certifikata: 09.05.2028 *Conformity assessment procedure: Annex IX, Chapter I, section 2 and 3 of Medical Devices Regulation (EU) 2017/745, date of issue:* 06.11.2024, *registration No:* HZ 1076832-1, *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*

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EN ISO 10993-5:2009 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 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 10993-18:2020 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*
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 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 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.*

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Celje, 07.11.2024
Place, Date

Anja Mavrič, B.Sc.
Person responsible for regulatory compliance (MDR, Article 15 (3): (b) & (c))

Signature:

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Verzija / *Version*: MDR 1

PRILOGA K IZJAVI O SKLADNOSTI VERZIJA MDR 1 – VSI REF / ANNEX TO DECLARATION OF CONFORMITY VERSION MDR 1 – ALL REF COVERED:

TRGOVSKO IME / TRADE NAME	KATALOŠKA ŠTEVILKA / CATALOGUE NUMBER	DOLŽINA / LENGTH	BARVA / COLOUR	PAKIRANJE / PACKAGING
SESALKE ZA SLINO / SALIVA EJECTORS	REF 709	15 cm	transparent	100 kos / pcs