UAB "Medicinos linija"
Aviacijos str. 28, LT-77103 Šiauliai, Lithuania
Reg. No.: 145889060
VAT No.: LT458890610

Tel.: +370 41 553 553
E-mail: info@i-dental.lt
Website: www.i-dental.lt

EU Declaration of Conformity

Name of manufacturer:	UAB "Medicinos linija"
Single registration number:	LT-MF-000002719
Basic UDI-DI	4772178ML10OMTG
Registered place of business and address of manufacturer:	Aviacijos str. 28, LT-77103 Siauliai, Lithuania
Date of issue of the declaration:	26th of May 2021
Place of issue:	Siauliai
Expiry date:	26th of May 2026

Medical device family:	Occlusion materials
Medical device name:	Occlusion spray
Intended use:	To restore dental chewing function; to protect biological structures. Occlusion spray is intended to test occlusal contacts and accurate fit of crowns and bridges in patient's mouth or on the model before fixing crowns and bridges in mouth for permanent use.

Medical device trade names and specification:

Medical device trade name	*Catalogue number (REF)*	*Specification*
i-OCCLUSPRAY	IOCKP	i-OCCLUSPRAY 75ml, green
dline Occlusion Spray	34000	dline Occlusion Spray 75ml, green

- This EU declaration of conformity is issued under the sole responsibility of the manufacturer.
- Risk class of the device:
  - Class I, according regulation (EU) 2017/745 of the European Parliament and of the Council Annex VIII, rule 5.
- Medical device complies with the fundamental requirements for medical devices listed in (EU) 2017/745 of the European Parliament and of the Council Annex I.
- Standards and common specifications applied:

EN ISO 13485:2016 Medical devices. Quality management systems. Requirements for regulatory purposes (ISO 13485:2016); EN ISO 13485:2016/AC:2018 Medical devices - Quality management

Bank: LUMINOR BANK AS
Konstitucijos ave. 21A, Vilnius, Lithuania
SWIFT: AGBLLT2XXXX
IBAN: LT62 4010 0510 0433 2852

Bank: AB SEB bankas
Gedimino ave. 12, Vilnius, Lithuania
SWIFT: CBVILT2X
IBAN: LT04 7044 0600 0235 9648

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systems - Requirements for regulatory purposes (ISO 13485:2016); EN ISO 14971: 2019 Medical devices - Application of risk management to medical devices (ISO 14971:2019); EN ISO 7405:2018 Dentistry - Evaluation of biocompatibility of medical devices used in dentistry (ISO 7405:2018, Corrected version 2018-12); EN ISO 10993-1:2018 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2018); EN ISO 10993-5:2009 Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:2009); EN ISO 10993-10:2010 Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization (ISO 10993-10:2010); EN ISO 10993-11:2017 Biological evaluation of medical devices – Part 11: Tests for systemic toxicity (ISO 10993-11:2017); EN ISO 10993-18:2009 Biological evaluation of medical devices – Part 18: Chemical characterization of materials (ISO 10993-18:2009); EN ISO 10993-19:2006 Biological evaluation of medical devices – Part 19: Physico-chemical, morphological and topographical characterization of materials (ISO 10993-19:2006); EN ISO 15223-1: 2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements (ISO 15223-1:2016, Corrected version 2017-03); EN 1041: 2008+A1:2013 Information supplied by the manufacturer of medical devices; EN 1641:2009 Dentistry - Medical devices for dentistry – Materials; MEDDEV 2.7/1 rev.4, 2016 Clinical evaluation: a guide for manufacturers and notified bodies under Directives 93/42/EEC and 90/385/EEC; MEDDEV 2.12/1 rev.8, 2013 Guidelines on a medical devices vigilance system; MEDDEV 2.12/2 rev.2, 2012 Post market clinical follow-up studies a guide for manufacturers and notified bodies; MEDDEV 2.2/3 rev.3, 1998 "USE-BY" date.

- Referenced technical documentation is retained under the premises of the manufacturer.

On behalf of UAB "Medicinos linija",

General Manager _____ Rima Žurauskaitė-Storace

Quality Executive Manager _____ Simona Daunienė

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