i-dental | Innovative Dental Products

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

EC Declaration of Conformity

Name of manufacturer: UAB „Medicinos linija"
Address of manufacturer: Aviacijos str. 28, LT-77103 Siauliai, Lithuania
Declaration date: 1st of September 2021
Declaration expiry date: 26th of May 2024

Notified body: BSI Group The Netherlands B.V., Notified Body No. 2797
Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, the Netherlands

Medical devices:

Medical device name	*Trade name*
Phosphoric acid etching gel and liquid	i-GEL N
	dline Phosphoric acid etching gel
	dline Phosphoric acid etching liquid
	OCTACID Green
	Blu-Gel
	elitis etch
	OCTACID Green Jeringa 12g (9ml)
	Bossklein MAXI Jumbo Etching Gel
	Bossklein Etching Gel Syringe

We herewith declare that:

- The above mentioned products meet the provisions of Council Directive 93/42/EEC Concerning Medical Devices amended by Directive 2007/47/EC of the European Parliament and of the Council (hereinafter Directive) and bear CE 2797 mark to indicate conformity of aforementioned products with the provisions of these Directives.
- The above mentioned products have been classified in IIa class according to Annex IX rule 6 of Directive.
- The Notified Body has assessed the conformity of medical devices and audited UAB „Medicinos linija" quality assurance system in accordance to Directive 93/42/EEC Concerning Medical Devices, Annex II excluding Section 4, as amended and found that the medical devices and quality assurance system meets the requirements (EC certificate No. CE 654572, Notified Body BSI Group The Netherlands B.V. (No. 2797)). This EC Declaration of Conformity has the same expiry date as the aforementioned EC Certificate.
- Referenced technical documentation is retained under the premises of the manufacturer.

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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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- Standards 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 systems. Requirements for regulatory purposes (ISO 13485:2016); EN ISO 14971: 2019 Medical devices. Application of risk management to medical devices (ISO 14971:2019); ISO 7405:2018 Dentistry - Evaluation of biocompatibility of medical devices used in dentistry (ISO 7405:2018); 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 10993-10:2013 Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization (ISO 10993-10:2010); EN ISO 10993-11:2018 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity (ISO 10993-11:2017); EN ISO 10993-18:2020 Biological evaluation of medical devices – Part 18: Chemical characterization of medical device materials within a risk management process (ISO 10993-18:2020); EN ISO/TS 10993-19:2020 Biological evaluation of medical devices — Part 19: Physico-chemical, morphological and topographical characterization of materials (ISO/TS 10993-19:2020); 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: 2016 rev.4 Clinical evaluation: Guide for manufacturers and notified bodies; MEDDEV 2.12/1: 2013 rev.8 Guidelines on a Medical devices Vigilance system; MEDDEV 2.12/2: 2012 rev.2 Guidelines on a Medical Devices Post Market Clinical Follow-Up Studies a Guide for Manufacturers and Notified Bodies; MEDDEV 2.2/3 rev.3, 1998 "USE-BY" date.

Document history

Revision date	Change description
2021-09-01	The address of the manufacturer has been updated from "Karaliauciaus str. 29, LT-78348 Siauliai, Lithuania" to "Aviacijos str. 28, LT-77103 Siauliai, Lithuania" due to changes of the Legal manufacturer production site location. However, medical device continues to comply with Directives and there are no significant changes in the design and intended purpose, thus such changes are allowed as per MDR Article 120 Transitional provisions.

General Manager _____ Rima Žurauskaitė-Storace

Quality Executive Manager _____ Simona Daunienė

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Annex 1.
List of various configurations/variants of the device that are intended to be made available on the market

Medical device name	*Medical device trade name*	*Catalogue number (REF)*	*Specification*
Phosphoric acid etching gel and liquid	**i-GEL N**	IGECP	4,3g syringe blue, 5 tips, instruction for use
		IGEGP	4,3g syringe green, 5 tips, instruction for use
		IGE12B	12g syringe blue, 10 tips, instruction for use
		IGE12G	12g syringe green, 10 tips, instruction for use
		IGE50B	42g syringe blue, 2x4,3g syringes blue, 20 tips, syringe connector, instruction for use
		IGE50G	42g syringe green, 2x4,3g syringes green, 20 tips, syringe connector, instruction for use
		IGEM1	4x1.2ml syringe blue, 10 tips, instruction for use
		IGEK1	4x4,3g syringe blue, 10 tips, instruction for use
		IGEK2	2x4,3g syringe blue, 5 tips, instruction for use
		IGEG1	4x4,3g syringe green, 10 tips, instruction for use
		IGESCP	1g syringe blue, 1 tip, instruction for use
		IGESP	0,5g syringe blue, 1 tip, instruction for use
		IGEGK	3ml bottle green, instruction for use
		IGEGL	5ml bottle green, instruction for use
		IGEGC	10ml bottle green, instruction for use
	dline Phosphoric Acid Etching Gel	20120	12g syringe blue, 10 tips, instruction for use
		20450	42g syringe blue, 2x4,3g syringes blue, 20 tips, syringe connector, instruction for use
		20043	4x4,3g syringe blue, 20 tips, instruction for use
		20040	4,3g syringe blue, 5 tips, instruction for use
	dline Phosphoric Acid Etching Liquid	20900	10ml bottle green, instruction for use
	OCTACID Green	C10671	4x3.5g syringes green, 10 tips, instruction for use
	OCTACID Green Jeringa 12g (9ml)	C10620 (04-072)	12g syringe blue, 10 tips, instruction for use
	Blu-Gel	C10670	3x3ml syringes blue, 10 tips, instruction for use
	elitis etch	QMSIGECP	4.3g syringe, blue, instruction for use
		QMSIGEM1	4x1.2ml syringe blue, 10 tips, instruction for use
		QMSIGE12	1.2ml syringe blue
		QMSIGE3	3ml syringe, blue
		QMSIGE25	25ml syringe, blue
		QMSIGE56B	2x25ml, 2x3ml syringes blue, 25 tips, syringe connector, instruction for use
	Bossklein MAXI Jumbo Etching Gel	BOS9904	60g syringe green, 50 tips, 5x3ml empty syringes, syringe connector, instruction for use
	Bossklein Etching Gel Syringe	BOS9903	12g syringe green, 25 tips, instruction for use

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