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*
Light curing nano flowable composite	i-FLOW N dline Light Curing Nano Flowable Composite OCTOLIGHT Flow elitis flow

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 8 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.
- 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, 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 10993-3:2014 Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity (ISO 10993-3:2014); EN ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:2009); EN ISO 10993-6:2016 Biological evaluation of medical devices

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– Part 6: Tests for local effects after implantation (ISO 10993-6:2016); 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 device; EN 1641:2009 Dentistry - Medical devices for dentistry – Materials; EN ISO 4049:2019 Dentistry – Polymer-based restorative materials (ISO 4049:2019); 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: 1998 rev.3 "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*
Light curing nano flowable composite	**i-FLOW N**	IFKA1	1.2g syringe shade A1, 3 tips, instruction for use
		IFTA1	2g syringe shade A1, 3 tips, instruction for use
		IFLA1	5g syringe shade A1, 5 tips, instruction for use
		IFSA2	0.5g syringe shade A2, 1 tip, instruction for use
		IFKA2	1.2g syringe shade A2, 3 tips, instruction for use
		IFTA2	2g syringe shade A2, 3 tips, instruction for use
		IFLA2	5g syringe shade A2, 5 tips, instruction for use
		IFSA3	0.5g syringe shade A3, 1 tip, instruction for use
		IFKA3	1.2g syringe shade A3, 3 tips, instruction for use
		IFTA3	2g syringe shade A3, 3 tips, instruction for use
		IFLA3	5g syringe shade A3, 5 tips, instruction for use
		IFKA35	1.2g syringe shade A3.5, 3 tips, instruction for use
		IFTA35	2g syringe shade A3.5, 3 tips, instruction for use
		IFLA35	5g syringe shade A3.5, 5 tips, instruction for use
		IFTB2	2g syringe shade B2, 3 tips, instruction for use
		IFLPN	5g syringe shade pink, 5 tips, instruction for use
		IFTPN	2g syringe shade pink, 3 tips, instruction for use
		IFLOG	5g syringe shade orange, 5 tips, instruction for use
		IFTOG	2g syringe shade orange, 3 tips, instruction for use
		IFLBL	5g syringe shade blue, 5 tips, instruction for use
		IFTBL	2g syringe shade blue, 3 tips, instruction for use

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Medical device name	*Medical device trade name*	*Catalogue number (REF)*	*Specification*
		IFTK1	4x2g syringes shades under request, 10 tips, instruction for use
	dline Light Curing Nano Flowable Composite	11010	4x2g syringe shade A1, 10 tips, instruction for use
		11020	4x2g syringe shade A2, 10 tips, instruction for use
		11021	0.5g syringe shade A2, 1 tips, instruction for use
		11030	4x2g syringe shade A3, 10 tips, instruction for use
		11031	0.5g syringe shade A3, 1 tip, , instruction for use
		11035	4x2g syringe shade A3.5, 10 tips, instruction for use
		11500	4x2g syringe shades: 2xA2, 2xA3, 10 tips, instruction for use
		11501	4x2g syringe shades: A1, A2, A3, A3.5, 10 tips, instruction for use
		11210	2g syringe shade A1, 3 tips, instruction for use
		11220	2g syringe shade A2, 3 tips, instruction for use
		11230	2g syringe shade A3, 3 tips, instruction for use
		11235	2g syringe shade A3.5, 3 tips, instruction for use
		11110	5g syringe shade A1, 5 tips, instruction for use
		11120	5g syringe shade A2, 5 tips, instruction for use
		11130	5g syringe shade A3, 5 tips, instruction for use
		11135	5g syringe shade A3.5, 5 tips, instruction for use
	OCTILIGHT Flow	C14630	2g syringe dentin shade A2, 3 tips, instruction for use
		C14730	2g syringe dentin shade A3, 3 tips, instruction for use
		C32530	2g syringe dentin shade A3.5, 3 tips, instruction for use
	elitis flow	RQMSIFTA1	2g syringe shade A1, 3 tips, instruction for use
		QMSIFTA2	2g syringe shade A2, 3 tips, instruction for use
		QMSIFTA3	2g syringe shade A3, 3 tips, instruction for use
		QMSIFTA35	2g syringe shade A3.5, 3 tips, instruction for use

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Medical device name	*Medical device trade name*	*Catalogue number (REF)*	*Specification*
		QMSIFTK1	4x2g syringes (2xA2, 2xA3), 10 tips, instruction for use

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