i-dental | Innovative Dental Products

UAB "Medicinos Linija"
Karaliaučiaus str. 29, LT-78374 Šiauliai, Lithuania
Reg. No.: 145889060
VAT No.: LT458890610

Tel.: +370 41 553 553
Fax: +370 41 553 551
E-mail: dental@i-dental.lt
Website: www.i-dental.lt

# EC Declaration of Conformity

**Name of manufacturer**: UAB „Medicinos linija"
**Address of manufacturer**: Karaliaučiaus str. 29, LT-78348 Šiauliai, Lithuania
**Declaration date**: 7th of September, 2018
**Declaration expiry date**: 15th of June, 2019

**Notified body**: BSI, Notified Body No. 0086
Kitemark Court, Davy Avenue, Knowhill, Milton Keynes MK5 8PP, UK

## Medical devices:

| *Medical devices* | *Type* | *Brand name* |
|---|---|---|
| Dental materials | | |
| | Light curing adhesive | i-BONDING LC N |
| | Chemical curing adhesive | i-BONDING CC N |
| | Temporary filling material | i-PRO N |
| | Resin modified zinc oxide-eugenol cement | i-ZOE N |
| | Root canal preparation solution | i-EDTA Solution |
| | Phosphoric acid etching gel and liquid | i-GEL N |
| | Light curing nano hybrid composite | i-LIGHT N |
| | | i-XCITE LC N |
| | Light curing temporary filling material | i-PRO LC |
| | Light curing compomer liner | i-LINER |
| | Chemical curing composite | i-XCITE CC N |
| | Light curing pit and fissure sealant | i-SEAL LC |
| | Light curing nano flowable composite | i-FLOW N |
| | Glass ionomer base lining cement | i-BAS |
| | Glass ionomer filling cement | i-FIL |
| | Light curing glass ionomer filling cement | i-FIL LC |
| | Glass ionomer luting cement | i-FIX |
| | Resin modified glass ionomer luting cement | i-FIX Plus |
| | Silver-glass ionomer cement | i-SIL |
| | | i-SOL |
| | Heat curing acrylic resin for dentures bases | i-PLAST HC |
| | Self curing acrylic resin for dentures repairs | i-PLAST CC |
| | Self curing acrylic resin for dentures casting | i-PLAST CA |



Bank: SWEDBANK AB
Konstitucijos ave. 20A, Vilnius, Lithuania
SWIFT: HABALT22
IBAN: LT50 7300 0101 1125 8200

Digitally signed by Gherasim Silvia
Date: 2021.09.06 14:14:15 EEST
Reason: MoldSign Signature
Location: Moldova

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

UAB "Medicinos Linija"
Karaliaučiaus str. 29, LT-78374 Šiauliai, Lithuania
Reg. No.: 145889060
VAT No.: LT458890610

Tel.: +370 41 553 553
Fax: +370 41 553 551
E-mail: dental@i-dental.lt
Website: www.i-dental.lt

| *Medical devices* | *Type* | *Brand name* |
|---|---|---|
| | Self curing acrylic resin for orthodontic | i-PLAST OR |
| | Acrylic teeth | i-DENT |
| | Zinc phosphate cement | i-PAC N |
| | Zinc polycarboxylate cement | i-POL N |

**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 0086 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 rules 5, 6, 7 and 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 (No. 0086)). 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:2016 Medical devices. Quality management systems. Requirements for regulatory purposes (ISO 13485:2016); EN ISO 14971: 2012 Medical devices. Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01); EN ISO 7405:2008 Dentistry - Evaluation of biocompatibility of medical devices used in dentistry (ISO 7405:2008); EN ISO 7405:2008/A1:2013 Dentistry - Evaluation of biocompatibility of medical devices used in dentistry (ISO 7405:2008/Amd.1:2013); EN ISO 10993-1:2009 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2009); EN ISO 10993-1:2009/AC:2010 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2009/Cor.1:2010); 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 – 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 10993-11:2017 Biological evaluation of medical devices – Part 11: Tests for systemic toxicity (ISO 10993-11:2017); EN ISO 15223-1:2016 Medical devices. Symbols to be used with medical device labels, labeling 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;*



Bank: SWEDBANK AB
Konstitucijos ave. 20A, Vilnius, Lithuania
SWIFT: HABALT22
IBAN: LT50 7300 0101 1126 2909



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

UAB "Medicinos Linija"
Karaliaučiaus str. 29, LT-78374 Šiauliai, Lithuania
Reg. No.: 145889060
VAT No.: LT458890610

Tel.: +370 41 553 553
Fax: +370 41 553 551
E-mail: dental@i-dental.lt
Website: www.i-dental.lt

*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; ISO/TS 11405:2015 Dentistry -- Testing of adhesion to tooth structure; EN ISO 3107:2011 Dentistry - Zinc oxide/eugenol cements and zinc oxide/non-eugenol cements (ISO 3107:2011); EN ISO 4049:2009 Dentistry - Polymer-based restorative materials (ISO 4049:2009); EN 1641:2009 Dentistry - Medical devices for dentistry – Materials; EN ISO 6874:2015 Dentistry – Polymer-based pit and fissure sealants (ISO 6874:2015); EN ISO 9917-1:2007 Dentistry - Water-based cements - Part 1: Powder/liquid acid-base cements (ISO 9917-1:2007); EN ISO 9917-2:2017 Dentistry - Water-based cements - Part 2: Resin-modified cements (ISO 9917-2:2017); EN ISO 22112:2017 Dentistry - Artificial teeth for dental prostheses (ISO 22112:2017); EN ISO 20795-1:2013 Dentistry – Base polymers – Part 1: Denture base polymers (ISO 20795-1:2013); EN ISO 20795-2:2013 Dentistry – Base polymers – Part 2: Orthodontic base polymers (ISO 20795-2:2013).*

LIETUVOS RESPUBLIKA UAB "MEDICINOS LINIJA" DOKUMENTAMS ŠIAULIAI

General Manager _____ Gintaras Dapkus

Quality Executive Manager _____ Geda Zuokaitė



Bank: SWEDBANK AB
Konstitucijos ave. 20A, Vilnius, Lithuania
SWIFT: HABALT22
IBAN: LT50 7300 0101 1126 2909



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