EC DECLARATION OF CONFORMITY
No. 02

We declare under our sole responsibility that the products stated herein are classified as **Class IIa** and
meet the requirements and provisions of the **93/42/EC** Medical Devices Directive

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EC CERTIFICATE NUMBER:	301021819CA
First Issue date:	29/06/2018
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Expire date:	28/06/2023

PRODUCTS: non-active dental devices refer to Annex 1.

CONFORMITY ASSESSMENT PROCEDURE: Full quality assurance

CLASSIFICATION: according to MDD 93/42/EEC, Annex IX, **Class IIa.**

HARMONIZED STANDARDS: see Annex 1.

Validity: 28/06/2023

Place: Dreieich
Date: 08/04/2020

DREIEICH TehnoDent TehnoDent GmbH

legally binding signature

Name: Mikhail Savchenko
Position: General Manager

Annex 1: ATTACHMENT TO EC DECLARATION OF CONFORMITY No. 02

No.	Product name	Rule	Harmonized Standard
I Glass Ionomer & Polymer Based Systems			
1.1	GlassyCem Radiopaque glass ionomer luting cement (powder-liquid)	8	EN 1641:2009 Dentistry – Medical devices for dentistry – Materials EN ISO 9917-1:2007 Dentistry – Water-based cements – Part 1: Powder/liquid acid-based cements
1.2	GlassyCem Radiopaque glass ionomer restorative cement (powder-liquid)		
1.3	GlassyCem for kids Radiopaque glass ionomer restorative cement (powder-liquid)		
1.4	GlassyCem Radiopaque glass ionomer luting cement (aqua-powder)		
1.5	GlassyCem Radiopaque glass ionomer restorative cement (aqua-powder)		
1.6	GlassyCem LC Light-curing radiopaque compomer		EN 1641:2009 Dentistry – Medical devices for dentistry – Materials EN ISO 4049:2009 Dentistry – Polymer-based restorative materials
1.7	GlassyCem Conditioner	6	EN 1641:2009 Dentistry – Medical devices for dentistry – Materials
1.8	GlassyCem Varnish	7	
1.9	ReLight Universal light-curing restorative composite	8	EN 1641:2009 Dentistry – Medical devices for dentistry – Materials EN ISO 4049:2009 Dentistry – Polymer-based restorative materials

No.	Product name	Rule	Harmonized Standard
1.10	ReLight colour Light-curing colour		EN 1641:2009 Dentistry – Medical devices for dentistry – Materials EN ISO 4049:2009 Dentistry – Polymer-based restorative materials
1.11	ReLight flow Light-curing flowable composite		
1.12	ReLight tempo Light-curing temporary filling composite		
1.13	ReLight tempo Light-curing flowable temporary filling composite		
1.14	ReLight Bond Light-curing single-component universal bonding agent	6	
1.15	ReLight P&B Light-curing two-component adhesive system		
II Water Based Cements			
2.1	A-Cem For fixation and filling	8	EN 1641:2009 Dentistry – Medical devices for dentistry – Materials EN ISO 9917-1:2007 Dentistry – Water-based cements – Part 1: Powder/liquid acid-based cements
III Hemostatics			
3.1	Hemostop Liquid for gingival retraction and hemostasis	6	EN 1641:2009 Dentistry – Medical devices for dentistry – Materials
3.2	Hemostop Gel for gingival retraction and hemostasis		
IV Retraction Cords			
4.1	Hemostop Retraction cord. For gingival retraction and hemostasis	6	EN 1641:2009 Dentistry – Medical devices for dentistry – Materials
V Root Canal's Filling Products			
5.1	Epoxidin	8	EN 1641:2009 Dentistry – Medical devices for
5.2	Rootdent Root canal repair product (powder or quick-hardening powder)		

No.	Product name	Rule	Harmonized Standard
5.4	Cupratin Powder		dentistry – Materials EN ISO 6876:2012 Dentistry – Root canals sealing materials
5.5	Cupratin Suspension No. 1	7	
5.6	Cupratin Suspension No. 2		
VI Temporary Filling Products			
6.1	Tempodent Paste	7	EN 1641:2009 Dentistry – Medical devices for dentistry – Materials EN ISO 3107:2011 Dentistry – Zinc oxide/eugenol cements and zinc oxide/noneugenol cements
VII Fluoridation Products			
7.1	Ftor-lux Kit. For deep-penetration fluoridation	7	EN 1641:2009 Dentistry – Medical devices for dentistry – Materials
VIII Antiseptic products for hard tooth tissues			
8.1	Antiseptic liquid No.2	6	EN 1641:2009 Dentistry – Medical devices for dentistry – Materials

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Name: Mikhail Savchenko

Position: General Manager