



## EC Declaration of Conformity

**Manufacturers Name:** TOR VM Ltd.

**Manufacturers Address:** Novatorov str., 7A, bld.2, room 44B, Moscow 119421, Russia  
Manufacturing site: Kulibina, 15c, Voronezh, 394029, Russia  
Telephone: +7 495 2255417

**SRN (Single Registration Number):** RU-MF-000016957

**Authorized Representative Name (if applicable):** Mr. Gregor Kostunov

**Authorized Representative Address (if applicable):** Untere Seegasse 54, DE-69124, Heidelberg, Germany  
Telephone: +49 (17) 626 400 019

**SRN (Single Registration Number):** DE-AR-000006585

**Basic UDI-DI:**

463003499DENFOR6F	Forceps
463003499MSHOLDDU	Matrix retainers
463003499CNTFORAF	Contact formers

**Name of the Device (s):** **Dental Matrix Band Retainers**  
Matrix retainers. Forceps. Contact formers  
*(Annex specifying List of Products is an integral part of this Declaration)*

**Product code:** GMDN 33204, Dental Matrix Band Retainer

**Classification:** Class I

**Notified Body name:** for Class I not relevant.

**Conformity assessment route:** Regulation (EU) 2017/745 (Class I, Rule 5), Annex IV, Assessment procedure according to Annex VIII, Rule 5, Regulation (EU) 2017/745;  
EN ISO 13485:2016/A11:2021, EN ISO 14971:2019/A11:2021, EN 1639:2009, EN ISO 10993-1:2020, EN ISO 10993-5:2009, EN ISO 10993-11:2018, EN ISO 10993-12:2021, EN 62366:2015, EN ISO 15223-1:2021.

This declaration of conformity is issued under the sole responsibility of TOR VM. We hereby declare that the medical device(s) specified above meet the provision of the Regulation (EU) 2017/745 for medical devices. All supporting documentation is retained at the premises of the manufacturer.

Signature:

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Dr. Oleg Mikhalev  
General manager

**Place and date (dd.mm.yyyy) of issue:**

Moscow, Russia  
03.08.2022



**List of Products**

Catalogue number	Product name
<b>Matrix retainers</b>	
1.022	Ring for Perforated Matrices
1.022b	Ring for Perforated Matrices
1.022c	Ring for Perforated Matrices
1.033	Ring for Saddle Matrices
1.033c	Ring for Saddle Matrices with Silicone Safety Cover
1.033A	Ring for Saddle Matrices
1.044	Slot Ring
1.044b	Slot Ring
1.044c	Slot Ring
1.088	Deciduous Ring
1.099(4)	Ring for Sectional Matrices, Low
1.099(5)	Ring for Sectional Matrices, Standard
1.099(6)	Ring for Sectional Matrices, High
1.099c	Ring for Sectional Matrices with Silicone Safety Cover
1.099A	Ring for Sectional Matrices
1.399	Ring Set
1.166	D Ring
1.166b	D Ring
1.166c	D Ring
1.167	MD Ring
1.167(4)	MD Ring
1.167(6)	MD Ring
1.167b	MD Ring
1.167c	MD Ring
1.177	M Ring
1.177b	M Ring
1.177c	M Ring
1.199	Ring for Sectional Matrices (with flat tines)
1.199b	Ring for Sectional Matrices (with flat tines)
1.199c	Ring for Sectional Matrices (with flat tines)
1.299	Delta Ring for Sectional Matrices
1.299b	Delta Ring for Sectional Matrices
1.299c	Delta Ring for Sectional Matrices
1.499	N Ring
1.599	W Ring
1.870	Fixing Kit Delta
1.002	Springclip for Perforated Matrices
1.003	Springclip for Saddle Matrices Small
1.004	Slot Springclip
1.005	Springclip for Saddle Matrices Large
1.103	Springclip
1.009	Springclip for Sectional Matrices
1.006	Ivory Retainer
1.007	Matrix Retainer
1.007M	Matrix Retainer



**List of Products**

Catalogue number	Product name
1.008	Matrix Retainer
1.008L	Matrix Retainer
1.008R	Matrix Retainer
1.014	Slot Retainer "Pin"
1.104	Slot Retainer "Cylinder"
1.114	Slot Retainer "Ring"
1.124	Slot Retainer "Handle"
1.444	Slot Retainer "Plate"
1.105	Anterior Strip Holder
1.105A	Anterior Strip Holder
1.106	Posterior Strip Holder
1.106A	Posterior Strip Holder
1.106B	Posterior Strip Holder
1.106C	Posterior Strip Holder
1.106D	Posterior Strip Holder
1.369	Do-All Proxicut Holder
1.369B	Do-All Proxicut Holder
1.369C	Do-All Proxicut Holder
1.369D	Do-All Proxicut Holder
1.369KT	Do-All Proxicut Kit
1.367KT	Do-All Proxicut Kit
1.370	Do-All Proxicut System
1.389	Proxicut Holder
1.100	Handle
1.107	Handle
1.108	Handle
1.109	Handle
<b>Forceps</b>	
1.099-1	Forceps
1.099-2	Forceps with Stoppers
1.099-3	Forceps
1.154	Linear Matrix Plier
1.164	Cross Matrix Plier
<b>Contact-formers</b>	
1.941	Contact Former
1.942	Contact Former
1.943	Contact Former
1.944	Contact Former
1.945	Contact Former
1.946	Contact Former
1.947	Contact Former
1.1941	Contact Former with Handle
1.1942	Contact Former with Handle
1.1943	Contact Former with Handle
1.1944	Contact Former with Handle
1.1945	Contact Former with Handle



**List of Products**

<b>Catalogue number</b>	<b>Product name</b>
1.1946	Contact Former with Handle
1.1947	Contact Former with Handle
1.1901	Contact Former
1.1902	Contact Former
1.1903	Contact Former
1.1904	Contact Former
1.1905	Contact Former
1.1906	Contact Former
1.1911	Contact Former
1.965	Contact and Shape Former

Dr. Oleg Mikhalev,  
General manager  
August 03, 2022