



EC Declaration of Conformity

Manufacturers Name: TOR VM Ltd.

Manufacturers Address: Novatorov str., 7A, bld.2, room 44B, Moscow 119421, Russia
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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
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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: TOR VM uses the following procedures for the CE-labeling of their products according the Regulation MDR 2017/745:
Class I: EC conformity declaration according to Annex IV, Rule 5 and
EN 1041:2008, EN ISO 13485:2016/AC:2018, ISO 14971:2019, EN 1639:2009, EN ISO 10993-1:2020, EN ISO 10993-5:2009, ISO 10993-10:2010, EN ISO 10993-11:2018, EN ISO 10993-12:2012, EN ISO 10993-18:2009, EN 62366-1:2008, BS EN ISO 15223-1:2016

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) MDR 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
27.12.2021



List of Products

Catalogue number	Product name
Matrix retainers	
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
1.293	Springclip
1.295	Springclip



List of Products

Catalogue number	Product name
1.006	Ivory Retainer
1.007	Matrix Retainer
1.007M	Matrix Retainer
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
1.105AB	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
1.106E	Posterior Strip Holder
3.106	Strip Holder
3.106A	Strip Holder
1.369	Do-All Proxicut Holder
1.369B	Do-All Proxicut Holder
1.369AB	Do-All Proxicut Holder
1.369CB	Do-All Proxicut Holder
1.369DB	Do-All Proxicut Holder
1.369KT	Do-All Proxicut Kit
1.367KT	Do-All Proxicut Kit
1.370	Do-All Proxicut System
1.379C	Proxicut Holder
1.379M	Proxicut Holder
1.379F	Proxicut Holder
1.379T	Proxicut Holder
1.389	Proxicut Holder
1.100	Handle
1.107	Handle
1.108	Handle
1.109	Handle
1.100T	Mirror Handle
Forceps	
1.099-1	Forceps
1.099-2	Forceps with Stoppers
1.099-3	Forceps



List of Products

Catalogue number	Product name
1.101	Tweezer
1.102	Tweezer
1.154	Linear Matrix Plier
1.164	Cross Matrix Plier
Contact-formers	
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
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 Mikhaley,
General manager
December 27, 2021

