



TOR VM Dental Manufacturing Company
Novatorov, 7A, bld.2, Moscow 119421, Russia
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Declaration of Conformity

Manufacturer: **TOR VM**
Address: Novatorov str., 7A, bld.2, Moscow 119421
Manufacturing site: Kulibina, 15s, Voronezh, 394000
Country: Russia
Telephone No. +7 495 2255417

Product ***Dental hand instruments***
(Annex specifying List of Products is an integral part of this Declaration)

The undersigned hereby declares, on behalf of the TOR VM, Novatorov str., 7A, bld.2, Moscow 119421, Russia, that the above-referenced product, to which this declaration relates, is in conformity with the provisions of:

Council Directive 93/42 EEC (Class I, Rule 5), Annex VII,
Assessment procedure according to Annex IX, Rule 5 MDD 93/42,
and

EN 1041:2008, EN ISO 13485: 2016, EN ISO 14971:2012, EN 1639:2009, EN ISO 10993-1:2009, EN ISO 10993-5:2009, EN ISO 10993-11:2009, EN ISO 10993-12:2009, EN 62366:2015, EN 980:2008, BS EN ISO 15223-1:2012.

The technical construction file required by MDD 93/42 directive is maintained at the corporate headquarters of **TOR VM** Novatorov str., 7A, bld. 2, Moscow, 119421, Russia, and its official EC representative **Mr. Gregor Kostunov**, Address: Untere Seegasse 54, DE-69124 Heidelberg, Germany.

Notified Body for Class I not relevant.

UMDNS Codes 16-667 Dental Hand Instruments, Other

Valid: unlimited
Place of issue: Moscow, Russia
Date of issue: 28.09.2018
Version 2 of 01.07.2019

Dr. Oleg Mikhalev
General manager



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Annex to Declaration of Conformity

List of Products

Catalogue number	Product name
1.010	Cotton roll holder – 1 pc.
1.941	Contact-former – 1pc.
1.942	Contact-former – 1pc.
1.943	Contact-former – 1pc.
1.944	Contact-former – 1pc.
1.945	Contact-former – 1pc.
1.946	Contact-former – 1pc.
1.947	Contact-former – 1pc.
1.1941	Contact-former – 1pc.
1.1942	Contact-former – 1pc.
1.1943	Contact-former – 1pc.
1.1944	Contact-former – 1pc.
1.1945	Contact-former – 1pc.
1.1946	Contact-former – 1pc.
1.1947	Contact-former – 1pc.
1.1901	Contact-former – 1pc.
1.1902	Contact-former – 1pc.
1.1903	Contact-former – 1pc.
1.1904	Contact-former – 1pc.
1.1911	Contact-former – 1pc.
3.908	Organizing board – 1pc.
3.909	Organizing board – 1pc.
3.912	Organizing board – 1pc.
3.401	Rubber dam frame – 1 pc.
3.402	Rubber dam frame – 1 pc.
3.403	Rubber dam frame – 1 pc.
3.401A	Rubber dam frame – 1 pc.
3.401B	Rubber dam frame – 1 pc.
3.402B	Rubber dam frame – 1 pc.
3.403B	Rubber dam frame – 1 pc.
3.910	Clamp organizer – 1 pc.
3.918	Clamp organizer – 1 pc.
1.105	Anterior strip holder – 1 pc.
1.106	Posterior strip holder – 1 pc.
1.107	Handle – 1 pc.
1.109	Handle – 1 pc.
1.154	Linear plier (L-plier) – 1 pc.
1.164	Cross plier (C-plier) – 1 pc.
1.369	Do-All proxicut holder: holder – 1 pc., key – 1 pc.
1.389	Proxicut holder – 1 pc.
1.369KT	Do-All proxicut kit: holder – 1 pc., key – 1 pc., handle – 1 pc.

Dr. Oleg Mikhalev
General manager
July 1, 2019