



TOR VM Dental Manufacturing Company

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Declaration of Conformity

Manufacturer: **TOR VM**
Address: Novatorov str., 7A, Moscow 119421
Manufacturing site: Kulibina, 15s, Voronezh, 394000
Country: Russia
Telephone No. +7 495 9367404

Product **Matrix Wedges**

The undersigned hereby declares, on behalf of the TOR VM, Novatorov str., 7A, 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 13485:2012, EN ISO 14971:2012, EN 1639:2009, EN ISO 10993-1:2009,
EN ISO 10993-5:2009, EN ISO 10993-11:2017, EN ISO 10993-12:2012, EN 62366:2015, 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, city Moscow, 119421, 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 16-370 Matrix Wedges, Dental

Date of the first CE mark: 10.08.2005
Valid: unlimited
Place of issue: Moscow, Russia
Date of issue: 10.08.2005
Version 5 of 18.01.2018

Dr. Oleg Mikhalev
General manager

