



## Declaration of Conformity

Manufacturer: **TOR VM Ltd.**  
SRN:  
Address: Novatorov str., 7A, bld.2, room 44B, Moscow 119421  
Manufacturing site: Kulibina, 15c, Voronezh, 394029  
Country: Russia  
Telephone No. +7 495 2255417

EC representative: Mr. Gregor Kostunov  
SRN: DE-AR-000006585  
Address: Untere Seegasse 54, DE-69124, Heidelberg  
Country: Germany  
Telephone: +49 (17) 626 400 019

Product ***Rubber Dam Kit***  
*(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, room 44B, Moscow 119421, Russia that the above-referenced product, to which this declaration relates, is in conformity with the provisions of:

Regulation (EU) 2017/745 (Class I, Rule 5), Annex IV,  
Assessment procedure according to Annex VIII, Rule 5, Regulation (EU) 2017/745,  
and  
EN 1041:2008, EN ISO 13485:2016/AC:2018, EN ISO 14971:2019, EN 1639:2009, EN ISO 10993-1:2009/AC:2010, EN ISO 10993-5:2009, ISO 10993-10:2010, EN ISO 10993-11:2018, EN ISO 10993-12:2012, EN ISO 10993-18:2020, EN 62366-1:2015, EN 980:2008, BS EN ISO 15223-1:2016, EN ISO 16635-1:2014, ISO 16635-2:2014.

The technical construction file required by Regulation (EU) 2017/745, is maintained at the corporate headquarters of **TOR VM Ltd.** address: Novatorov str., 7A, bld. 2, room 44B, 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.

**GMDN codes** 45000, Rubber Dam Kit

Valid: unlimited  
Place of issue: Moscow, Russia  
Date of issue: 26.05.2021

  
Dr. Oleg Mikhalev  
General manager





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List of Products

Catalogue number			Product name
<b>Dental Rubber Dam Clamps</b>			
<b>Standard</b>	<b>Black</b>	<b>Mate</b>	
0	0-B	0-M	Clamp
00	00-B	00-M	Clamp
W9	W9-B	W9-M	Clamp
9	9-B	9-M	Clamp
212	212-B	212-M	Clamp
210	210-B	210-M	Clamp
W2	W2-B	W2-M	Clamp
2	2-B	2-M	Clamp
W2A	W2A-B	W2A-M	Clamp
2A	2A-B	2A-M	Clamp
138	138-B	138-M	Clamp
139	139-B	139-M	Clamp
W3	W3-B	W3-M	Clamp
W7	W7-B	W7-M	Clamp
7	7-B	7-M	Clamp
W8A	W8A-B	W8A-M	Clamp
8	8-B	8-M	Clamp
8A	8A-B	8A-M	Clamp
12A	12A-B	12A-M	Clamp
13A	13A-B	13A-M	Clamp
14	14-B	14-M	Clamp
14A	14A-B	14A-M	Clamp
24	24-B	24-M	Clamp
25	25-B	25-M	Clamp
W56	W56-B	W56-M	Clamp
B1	B1-B	B1-M	Clamp
B2	B2-B	B2-M	Clamp
B3	B3-B	B3-M	Clamp
B4	B4-B	B4-M	Clamp
B5	B5-B	B5-M	Clamp
B6	B6-B	B6-M	Clamp
P1	P1-B	P1-M	Clamp
P2	P2-B	P1-M	Clamp
1	1-B	1-M	Clamp
22	22-B	22-M	Clamp
23	23-B	23-M	Clamp
54	54-B	54-M	Clamp
55	55-B	55-M	Clamp
64	64-B	64-M	Clamp
65	65-B	65-M	Clamp
74	74-B	74-M	Clamp
75	75-B	75-M	Clamp



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Catalogue number			Product name
Standard	Black	Mate	
84	84-B	84-M	Clamp
85	85-B	85-M	Clamp
201	210-B	201-M	Clamp
202	202-B	202-M	Clamp
3.007			Clamps
3.008			Clamps
3.009			Clamps
3.010			Clamps
3.011			Clamps
3.014			Clamps
3.015			Clamps
3.016			Deciduous Clamps
3.017			Clamps
3.018			Clamps
3.019			Clamps
<b>Clamp Organizers</b>			
3.908			Clamp Organizer for 8 Clamps
3.910			Clamp Organizer for 10 Clamps
3.909			Clamp Organizer for 9 Clamps
3.912			Clamp Organizer for 12 Clamps
3.918			Clamp Organizer for 18 Clamps
<b>Rubber Dam Frames</b>			
3.401			Rubber Dam Frame 93x91 mm
3.402			Rubber Dam Frame 110x100 mm
3.403			Rubber Dam Frame 128x125 mm
3.401A			Deciduous Rubber Dam Frame 96x73 mm
3.401B			Rubber Dam Frame 93x91 mm with Floss Retainer
3.402B			Rubber Dam Frame 110x100 mm with Floss Retainer
3.403B			Rubber Dam Frame 128x125 mm with Floss Retainer
<b>Rubber Dam Forceps</b>			
3.991			Rubber Dam Forceps
3.992			Rubber Dam Forceps
3.993			Rubber Dam Forceps
<b>Rubber Dam Punchers</b>			
3.998			Rubber Dam Puncher
3.999			Rubber Dam Puncher

Dr. Oleg Mikhalev  
General manager  
May 26, 2021

