



Dental Manufacturing Company
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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:
463003499RUBCLAD7 Rubber dam clamps
463003499RUBFOREZ Rubber dam forceps
463003499RUBFRAE8 Rubber dam frames
463003499RUBORGFZ Clamp organizers
463003499RUBPUNGV Rubber dam puncher

Name of the Device (s): **Rubber Dam Kit**
Rubber dam clamps. Rubber dam forceps. Rubber dam frames.
Rubber dam punchers. Clamp organizers
(Annex specifying List of Products is an integral part of this Declaration)

Product code: 45000, Rubber Dam Kit

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 03.08.2022



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List of Products

Catalogue number			Product name
Dental Rubber Dam Clamps			
Standard	Black	Mate	
0	0-B	0-M	Clamp
00	00-B	00-M	Clamp
W00	W00-B	W00-M	Clamp
1	1-B	1-M	Clamp
1A	1A-B	1A-M	Clamp
1T	1T-B	1T-M	Clamp
1AT	1AT-B	1AT-M	Clamp
W1	W1-B	W1-M	Clamp
2	2-B	2-M	Clamp
2A	2A-B	2A-M	Clamp
2AD	2AD-B	2AD-M	Clamp
2T	2T-B	2T-M	Clamp
2AT	2AT-B	2AT-M	Clamp
W2	W2-B	W2-M	Clamp
W2A	W2A-B	W2A-M	Clamp
3	3-B	3-M	Clamp
W3	W3-B	W3-M	Clamp
4	4-B	4-M	Clamp
W4	W4-B	W4-M	Clamp
5	5-B	5-M	Clamp
6	6-B	6-M	Clamp
7	7-B	7-M	Clamp
7A	7A-B	7A-M	Clamp
W7	W7-B	W7-M	Clamp
8	8-B	8-M	Clamp
8A	8A-B	8A-M	Clamp
8AD	8AD-B	8AD-M	Clamp
W8	W8-B	W8-M	Clamp
W8A	W8A-B	W8A-M	Clamp
9	9-B	9-M	Clamp
9T	9T-B	9T-M	Clamp
W9	W9-B	W9-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
14T	14T-B	14T-M	Clamp
W14A	W14A-B	W14A-M	Clamp
15	15-B	15-M	Clamp
18	18-B	18-M	Clamp
22	22-B	22-M	Clamp
23	23-B	23-M	Clamp
24	24-B	24-M	Clamp
25	25-B	25-M	Clamp
26	26-B	26-M	Clamp
27N	27N-B	27N-M	Clamp
28	28-B	28-M	Clamp
29	29-B	29-M	Clamp



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List of Products. Continued

Catalogue number			Product name
Dental Rubber Dam Clamps			
Standard	Black	Mate	
30	30-B	30-M	Clamp
31	31-B	31-M	Clamp
41	41-B	41-M	Clamp
42	42-B	42-M	Clamp
43	43-B	43-M	Clamp
44	44-B	44-M	Clamp
51	51-B	51-M	Clamp
56	56-B	56-M	Clamp
56T	56T-B	56T-M	Clamp
W56	W56-B	W56-M	Clamp
90N	90N-B	90N-M	Clamp
138	138-B	138-M	Clamp
139	139-B	139-M	Clamp
200	200-B	200-M	Clamp
201	201-B	201-M	Clamp
202	202-B	202-M	Clamp
203	203-B	203-M	Clamp
204	204-B	204-M	Clamp
205	205-B	205-M	Clamp
206	206-B	206-M	Clamp
207	207-B	207-M	Clamp
208	208-B	208-M	Clamp
209	209-B	209-M	Clamp
210	210-B	210-M	Clamp
211	211-B	211-M	Clamp
212	212-B	212-M	Clamp
215			Clamp
216			Clamp
P-1	P-1-B	P-1-M	Clamp
P-2	P-2-B	P-2-M	Clamp
G-1	G-1-B	G-1-M	Clamp
G-2	G-2-B	G-2-M	Clamp
S-G	S-G-B	S-G-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
84	84-B	84-M	Clamp
85	85-B	85-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
3.007			Clamps



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List of Products. Continued

Catalogue number	Product name
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
Clamp Organizers	
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
Rubber Dam Frames	
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
Rubber Dam Forceps	
3.991	Rubber Dam Forceps
3.992	Rubber Dam Forceps
3.993	Rubber Dam Forceps
Rubber Dam Punchers	
3.998	Rubber Dam Puncher
3.999	Rubber Dam Puncher

Dr. Oleg Mikhalev,
General manager
August 03, 2022