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Declaration of Conformity

Manufacturer: **TOR VM**
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Manufacturing site: Kulibina, 15s, Voronezh, 394000
Country: Russia
Telephone No. +7 495 9367404, +7 495 2255417

Product ***Dental Polishing Discs and Mandrels***
(Annex specifying List of Products is an integral part of this Declaration)

The undersigned hereby declares, on behalf of the TOR VM, Novatorov, 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 IIa, Rule 5), Annex II (excluding section 4), Section 3.
Assessment procedure according to Annex II, 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 15223-1:2016.

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

Notified Body number 2195, **SZUTEST**, Certificate number **2195-MED-1326801**

Address: Szutest Uygunluk Değerlendirme A.Ş. Yukarı Dudullu Mh. Nato Yolu Cd. Çam Sk. No:7
Ümraniye, İstanbul, TÜRKİYE

UMDNS Codes 11282 Disks. Dental
12429 Mandrels

Date of the first CE mark: 25.09.2013
Valid: 17.09.2021
Date of the first lot: 30.09.2013
Place of issue: Moscow, Russia
Date of issue: 23.08.2013
Version 7 of 18.09.2018

Dr. Oleg Mikhalev
General manager



List of Products

Catalogue number	Product name
1.111	Mandrel for stem polishing discs RA type - 1 pc.
1.110	Mandrel for stem polishing discs HP type - 1 pc.
1.115	Mandrel for stem polishing discs RA type - 1 pc.
1.600	<p>Stem discs including:</p> <ul style="list-style-type: none"> - stem polishing discs for gross reduction: <ul style="list-style-type: none"> 8 mm in diameter (catalogue number 1.611) - 10 pcs., 12 mm in diameter (catalogue number 1.621) - 10 pcs., 14 mm in diameter (catalogue number 1.631) - 10 pcs., - stem polishing discs for contouring: <ul style="list-style-type: none"> 8 mm in diameter (catalogue number 1.612) - 10 pcs., 12 mm in diameter (catalogue number 1.622) - 10 pcs., 14 mm in diameter (catalogue number 1.632) - 10 pcs., - stem polishing discs for finishing: <ul style="list-style-type: none"> 8 mm in diameter (catalogue number 1.613) - 10 pcs., 12 mm in diameter (catalogue number 1.623) - 10 pcs., 14 mm in diameter (catalogue number 1.633) - 10 pcs., - stem polishing discs for polishing: <ul style="list-style-type: none"> 8 mm in diameter (catalogue number 1.614) - 10 pcs., 12 mm in diameter (catalogue number 1.624) - 10 pcs., 14 mm in diameter (catalogue number 1.634) - 10 pcs., - stem polishing discs with back abrasive position 14 mm in diameter: <ul style="list-style-type: none"> for gross reduction (catalogue number 1.631o) - 10 pcs., for contouring (catalogue number 1.632o) - 10 pcs., for finishing (catalogue number 1.633o) - 10 pcs., for polishing (catalogue number 1.634o) - 10 pcs., - mandrel of RA type for stem polishing discs (catalogue number 1.111) - 1 pc.
1.610	<p>Stem polishing discs including:</p> <ul style="list-style-type: none"> - stem polishing discs 8 mm in diameter: <ul style="list-style-type: none"> for gross reduction (catalogue number 1.611) - 10 pcs., for contouring (catalogue number 1.612) - 10 pcs., for finishing (catalogue number 1.613) - 10 pcs., for polishing (catalogue number 1.614) - 10 pcs., - mandrel of RA type for stem polishing discs (catalogue number 1.111) - 1 pc.
1.620	<p>Stem polishing discs including:</p> <ul style="list-style-type: none"> - stem polishing discs 12 mm in diameter: <ul style="list-style-type: none"> for gross reduction (catalogue number 1.621) - 10 pcs., for contouring (catalogue number 1.622) - 10 pcs., for finishing (catalogue number 1.623) - 10 pcs., for polishing (catalogue number 1.624) - 10 pcs., - mandrel of RA type for stem polishing discs (catalogue number 1.111) - 1 pc.
1.630	<p>Stem polishing discs including:</p> <ul style="list-style-type: none"> - stem polishing discs 14 mm in diameter: <ul style="list-style-type: none"> for gross reduction (catalogue number 1.631) - 10 pcs., for contouring (catalogue number 1.632) - 10 pcs., for finishing (catalogue number 1.633) - 10 pcs., for polishing (catalogue number 1.634) - 10 pcs., - mandrel of RA type for stem polishing discs (catalogue number 1.111) - 1 pc.

1.020D	Finishing and Polishing kit including: - stem polishing discs 14 mm in diameter: for gross reduction (catalogue number 1.631) - 12 pcs., for contouring (catalogue number 1.632) - 12 pcs., for finishing (catalogue number 1.633) - 12 pcs., for polishing (catalogue number 1.634) - 12 pcs., - mandrel of RA type for stem polishing discs (catalogue number 1.111) - 1 pc.
1.611	Stem discs for gross reduction 8 mm in diameter - 40 pcs.
1.621	Stem discs for gross reduction 12 mm in diameter - 40 pcs.
1.631	Stem discs for gross reduction 14 mm in diameter - 40 pcs.
1.612	Stem discs for contouring 8 mm in diameter - 40 pcs.
1.622	Stem discs for contouring 12 mm in diameter - 40 pcs.
1.632	Stem discs for contouring 14 mm in diameter - 40 pcs.
1.613	Stem discs for finishing 8 mm in diameter - 40 pcs.
1.623	Stem discs for finishing 12 mm in diameter - 40 pcs.
1.633	Stem discs for finishing 14 mm in diameter - 40 pcs.
1.614	Stem discs for polishing 8 mm in diameter - 40 pcs.
1.624	Stem discs for polishing 12 mm in diameter - 40 pcs.
1.634	Stem discs for polishing 14 mm in diameter - 40 pcs.
1.650	Stem polishing discs including: - stem polishing discs 8 mm in diameter: for gross reduction (catalogue number 1.651(8)) - 4 pcs., for contouring (catalogue number 1.652(8)) - 4 pcs., for finishing (catalogue number 1.653(8)) - 4 pcs., for polishing (catalogue number 1.644(8)) - 4 pcs., - stem polishing discs 12 mm in diameter: for gross reduction (catalogue number 1.651(12)) - 4 pcs., for contouring (catalogue number 1.652(12)) - 4 pcs., for finishing (catalogue number 1.653(12)) - 4 pcs., for polishing (catalogue number 1.644(12)) - 4 pcs., - mandrel of RA type for stem polishing discs (catalogue number 1.115) - 1 pc
1.651(8)	Stem polishing discs for gross reduction 8 mm in diameter - 40 pcs.
1.651(12)	Stem polishing discs for gross reduction 12 mm in diameter - 40 pcs.
1.651(14)	Stem polishing discs for gross reduction 14 mm in diameter - 40 pcs.
1.652(8)	Stem polishing discs for contouring 8 mm in diameter - 40 pcs.
1.652(12)	Stem polishing discs for contouring 12 mm in diameter - 40 pcs.
1.652(14)	Stem polishing discs for contouring 14 mm in diameter - 40 pcs.
1.653(8)	Stem polishing discs for finishing 8 mm in diameter - 40 pcs.
1.653(12)	Stem polishing discs for finishing 12 mm in diameter - 40 pcs.
1.653(14)	Stem polishing discs for finishing 14 mm in diameter - 40 pcs.
1.654(8)	Stem polishing discs for polishing 8 mm in diameter - 40 pcs.
1.654(12)	Stem polishing discs for polishing 12 mm in diameter - 40 pcs.
1.654(14)	Stem polishing discs for polishing 14 mm in diameter - 40 pcs.
1.611o	Stem polishing discs for gross reduction with back abrasive position 8 mm in diameter - 40 pcs.
1.621o	Stem polishing discs with back abrasive position 12 mm in diameter - 40 pcs.
1.631o	Stem polishing discs with back abrasive position 14 mm in diameter - 40 pcs.
1.612o	Stem polishing discs for contouring with back abrasive position 8 mm in diameter - 40 pcs.
1.622o	Stem polishing discs for contouring with back abrasive position 12 mm in diameter - 40 pcs.

1.632o	Stem polishing discs for contouring with back abrasive position 14 mm in diameter - 40 pcs.
1.613o	Stem polishing discs for finishing with back abrasive position 8 mm in diameter - 40 pcs.
1.623o	Stem polishing discs for finishing with back abrasive position 12 mm in diameter - 40 pcs.
1.633o	Stem polishing discs for finishing with back abrasive position 14 mm in diameter - 40 pcs.
1.614o	Stem polishing discs for polishing with back abrasive position 8 mm in diameter - 40 pcs.
1.624o	Stem polishing discs for polishing with back abrasive position 12 mm in diameter - 40 pcs.
1.634o	Stem polishing discs for polishing with back abrasive position 14 mm in diameter - 40 pcs.
1.651(8)o	Stem polishing discs for gross reduction with back abrasive position 8 mm in diameter - 40 pcs.
1.651(12)o	Stem polishing discs for gross reduction with back abrasive position 12 mm in diameter - 40 pcs.
1.651(14)o	Stem polishing discs for gross reduction with back abrasive position 14 mm in diameter - 40 pcs.
1.652(8)o	Stem polishing discs for contouring with back abrasive position 8 mm in diameter - 40 pcs.
1.652(12)o	Stem polishing discs for contouring with back abrasive position 12 mm in diameter - 40 pcs.
1.652(14)o	Stem polishing discs for contouring with back abrasive position 14 mm in diameter - 40 pcs.
1.653(8)o	Stem polishing discs for finishing with back abrasive position 8 mm in diameter - 40 pcs.
1.653(12)o	Stem polishing discs for finishing with back abrasive position 12 mm in diameter - 40 pcs.
1.653(14)o	Stem polishing discs for finishing with back abrasive position 14 mm in diameter - 40 pcs.
1.654(8)o	Stem polishing discs for polishing with back abrasive position 8 mm in diameter - 40 pcs.
1.654(12)o	Stem polishing discs for polishing with back abrasive position 12 mm in diameter - 40 pcs.
1.654(14)o	Stem polishing discs for polishing with back abrasive position 14 mm in diameter - 40 pcs.
1.021D	Finishing and Polishing kit including: - polishing discs 14 mm in diameter: for gross reduction (catalogue number 1.731(14)) - 12 pcs., for contouring (catalogue number 1.732(14)) - 12 pcs., for finishing (catalogue number 1.733(14)) - 12 pcs., for polishing (catalogue number 1.734(14)) - 12 pcs., - mandrel of RA type for polishing discs (catalogue number 1.121) - 1 pc.
1.075	Polishing discs including: - polishing discs 14 mm in diameter: for gross reduction (catalogue number 1.731(14)) - 10 pcs., for contouring (catalogue number 1.732(14)) - 10 pcs., for finishing (catalogue number 1.733(14)) - 10 pcs., for polishing (catalogue number 1.734(14)) - 10 pcs., - polishing discs 12 mm in diameter: for gross reduction (catalogue number 1.731(12)) - 10 pcs., for contouring (catalogue number 1.732(12)) - 10 pcs., for finishing (catalogue number 1.733(12)) - 10 pcs., for polishing (catalogue number 1.734(12)) - 10 pcs., - mandrel of RA type for polishing discs (catalogue number 1.121) - 1 pc.
1.076	Polishing discs including: - polishing discs 14 mm in diameter:

	<p>for gross reduction (catalogue number 1.731(14)) - 30 pcs., for contouring (catalogue number 1.732(14)) - 30 pcs., for finishing (catalogue number 1.733(14)) - 30 pcs., for polishing (catalogue number 1.734(14)) - 30 pcs., - polishing discs 12 mm in diameter: for gross reduction (catalogue number 1.731(12)) - 30 pcs., for contouring (catalogue number 1.732(12)) - 30 pcs., for finishing (catalogue number 1.733(12)) - 30 pcs., for polishing (catalogue number 1.734(12)) - 30 pcs., - mandrel of RA type for polishing discs (catalogue number 1.121) - 1 pc.</p>
1.077	<p>Polishing discs including: - polishing discs 9,3 mm in diameter: for gross reduction (catalogue number 1.731(A)) - 30 pcs., for contouring (catalogue number 1.732(A)) - 30 pcs., for finishing (catalogue number 1.733(A)) - 30 pcs., for polishing (catalogue number 1.734(A)) - 30 pcs., - polishing discs 12,7 mm in diameter: for gross reduction (catalogue number 1.731(B)) - 30 pcs., for contouring (catalogue number 1.732(B)) - 30 pcs., for finishing (catalogue number 1.733(B)) - 30 pcs., for polishing (catalogue number 1.734(B)) - 30 pcs., - mandrel of RA type for polishing discs (catalogue number 1.121) - 1 pc.</p>
1.069	<p>Polishing discs including: - polishing discs 10 mm in diameter: for gross reduction (catalogue number 1.731(10)) - 10 pcs., for contouring (catalogue number 1.732(10)) - 10 pcs., for finishing (catalogue number 1.733(10)) - 10 pcs., for polishing (catalogue number 1.734(10)) - 10 pcs., - mandrel of RA type for polishing discs (catalogue number 1.121) - 1 pc.</p>
1.070	<p>Polishing discs including: - polishing discs 12 mm in diameter: for gross reduction (catalogue number 1.731(12)) - 10 pcs., for contouring (catalogue number 1.732(12)) - 10 pcs., for finishing (catalogue number 1.733(12)) - 10 pcs., for polishing (catalogue number 1.734(12)) - 10 pcs., - mandrel of RA type for polishing discs (catalogue number 1.121) - 1 pc.</p>
1.071	<p>Polishing discs including: - polishing discs 14 mm in diameter: for gross reduction (catalogue number 1.731(14)) - 10 pcs., for contouring (catalogue number 1.732(14)) - 10 pcs., for finishing (catalogue number 1.733(14)) - 10 pcs., for polishing (catalogue number 1.734(14)) - 10 pcs., - mandrel of RA type for polishing discs (catalogue number 1.121) - 1 pc.</p>
1.072	<p>Polishing discs including: - polishing discs 16 mm in diameter: for gross reduction (catalogue number 1.731(16)) - 10 pcs., for contouring (catalogue number 1.732(16)) - 10 pcs., for finishing (catalogue number 1.733(16)) - 10 pcs., for polishing (catalogue number 1.734(16)) - 10 pcs., - mandrel of RA type for polishing discs (catalogue number 1.121) - 1 pc.</p>
1.731(A)	Polishing discs for gross reduction 9,3 mm in diameter - 50 pcs.
1.731(10)	Polishing discs for gross reduction 10 mm in diameter - 40 pcs.

1.731(12)	Polishing discs for gross reduction 12 mm in diameter - 40 pcs.
1.731(B)	Polishing discs for gross reduction 12,7 mm in diameter - 50 pcs.
1.731(14)	Polishing discs for gross reduction 14 mm in diameter - 40 pcs.
1.731(16)	Polishing discs for gross reduction 16 mm in diameter - 40 pcs.
1.732(A)	Polishing discs for contouring 9,3 mm in diameter - 50 pcs.
1.732(10)	Polishing discs for contouring 10 mm in diameter - 40 pcs.
1.732(12)	Polishing discs for contouring 12 mm in diameter - 40 pcs.
1.732(B)	Polishing discs for contouring 12,7 mm in diameter - 50 pcs.
1.732(14)	Polishing discs for contouring 14 mm in diameter - 40 pcs.
1.732(16)	Polishing discs for contouring 16 mm in diameter - 40 pcs.
1.733(A)	Polishing discs for finishing 9,3 mm in diameter - 50 pcs.
1.733(10)	Polishing discs for finishing 10 mm in diameter - 40 pcs.
1.733(12)	Polishing discs for finishing 12 mm in diameter - 40 pcs.
1.733(B)	Polishing discs for finishing 12,7 mm in diameter - 50 pcs.
1.733(14)	Polishing discs for finishing 14 mm in diameter - 40 pcs.
1.733(16)	Polishing discs for finishing 16 mm in diameter - 40 pcs.
1.734(A)	Polishing discs for polishing 9,3 mm in diameter - 50 pcs.
1.734(10)	Polishing discs for polishing 10 mm in diameter - 40 pcs.
1.734(12)	Polishing discs for polishing 12 mm in diameter - 40 pcs.
1.734(B)	Polishing discs for polishing 12,7 mm in diameter - 50 pcs.
1.734(14)	Polishing discs for polishing 14 mm in diameter - 40 pcs.
1.734(16)	Polishing discs for polishing 16 mm in diameter - 40 pcs.
1.120	Mandrel of HP type for polishing discs - 1 pc.
1.121	Mandrel of RA type for polishing discs - 1 pc.