

DECLARATION OF CONFORMITY

Manufacturer

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declare on our own responsibility that Medical Devices

- 1) Fixing wedges (both wooden and plastic) UMDNS Nr. 16-370
- 2) Polishing Strips UMDNS Nr.16-201
- 3) Matrices and Matrix Bands UMDNS Nr.16-195
- 4) Rubber Dams, Dental UMDNS Nr.11-155
- 5) Dental Hand Instrument UMDNS Nr.11-160

are auxiliary materials for filling procedure in dentistry and all the above devices meet all the provisions of the Directive 93/42/EEC which apply to them

Applied standards 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 10993-11:2009, EN ISO 10993-12:2009, EN 62366:2015, EN 980:2008, BS EN ISO 15223-1:2012

Notified body (if applicable) : for class I not relevant

Conformity assessment procedure : Council Directive 93/42 EEC, Annex VII (Class I, Annex IX, Rule 5)

The complete list of products with their description are in the Annex 1 which is the part of Declaration of Conformity.

Date of the first CE mark : August 10, 2005

Date of the first lot : October 25, 2010

Moscow, May 17, 2017

Dr. Oleg Mikhalev
CEO,
TOR VM



A handwritten signature in blue ink, appearing to be "Oleg Mikhalev".

Matrices and Accessories for Dental Filling Modelling «TOR VM»

according to Technical File 9391-006-49962851-2005

Registration Certificate № FCR 2010/07780**Issued on January 29, 2016 by Federal Service on Surveillance in Health Care (ROSZDRAVNADZOR), Russian Federation****Matrices****Intended use:** dental filling modeling, to prevent contact between teeth during manipulations of the dentist, to be placed around the tooth**Transparent (mylar) matrix bands (separate, in striprolls, with and without stopper)**

Transparent strips	1.040, 1.041, 1.141	Strips 100 mm long, 8 / 10 mm wide Transparent cervical matrix bands
Transparent striprolls	1.240, 1.241, 1.242, 1.243, 1.244, 1.245	Transparent strips 10 m long 8 / 10 mm wide packed in rolls (different packages)
Transparent stopstrips	1.440, 1.441	Transparent strips 100 mm long, 8 / 10 mm wide with stoppers on one end-side

Transparent (mylar) contoured matrices with and without clamp (fixing ring), and also closed and with fixing glue layer

Transparent (mylar) contoured matrices	1.090, 1.190, 1.091, 1.191, 1.092	Premolar matrices of 1 / 4 shapes Molars matrices of 1 / 4 shapes Kit of molar&premolar matrices
Transparent (mylar) contoured matrices combined with clamp	1.094, 1.194, 1.095, 1.195, 1.095(2+), 1.096	Premolar matrices of 1 / 4 shapes Molars matrices of 1 / 4 shapes Matrices for gross molars Kit of molar&premolar matrices
Self-adhesive transparent (mylar) contoured matrices	1.490, 1.491	Premolar and molar transparent contoured matrices with glue layers on the end-sides
Sectional transparent (mylar) contoured matrices	1.922, 1.923	Narrow and wide sectional matrices
Transparent (mylar) crowns (closed matrices)	1.901, 1.903, 1.905, 1.907, 1.908, 1.909 1.910, 1.911, 1.912 1.915	Crowns on plates (to be cut off) for various parts of incisors, canines, molars and premolars Kits of cut-off crowns for anteriors and posteriors and deciduous crowns Kit of conical crowns of 8 types

Metal contoured and plain matrices, perforated and non-perforated (separate and in striprolls), with and without clamp (fixing ring)*Metal contoured matrices including*

Metal contoured matrices	1.501, 1.502, 1.503, 1.504, 1.505, 1.506, 1.507, 1.508 1.500, 1.500+	Premolar matrices of 1 shape Premolar matrices of 4 shapes
	1.511, 1.512, 1.513, 1.514, 1.515, 1.516,	Molars matrices of 1 shape

	1.517, 1.518	
	1.510, 1.510 +	Molar matrices of 4 shapes
Metal contoured matrices combined with clamp (fixing ring)	1.541, 1.542, 1.543, 1.544, 1.545, 1.549, 1.540,	Premolar matrices of 1 shape
	1.551, 1.552, 1.553,	Premolar matrices of 4 shapes
	1.554, 1.555, 1.559,	Molars matrices of 1 shape
	1.550,	Molar matrices of 4 shapes
	1.560	Premolar & molar matrices of 1 shape
Saddle contoured metal matrices	1.311, 1.312, 1.313,	Contoured matrices with cylinder-shape tubes at the edges
	1.310,	Matrices of 3 types with springclip 1.003
	1.320	Matrices of 3 types with ring 1.033
	1.330	Matrices of 9 types with springclip 1.003
Matrices "Pony"	1.341, 1.343,	Contoured matrices of 1 type with ledge
	1.342, 1.344,	Contoured matrices of 1 type without ledge
	1.340,	Matrices of 4 types with springclip 1.044
	1.350	Matrices of 4 types with ring 1.004
Perforated metal contoured matrices	1.531(1), 1.531(2), 1.531(3), 1.531(4), 1.531(5)	Perforated contoured matrices of 1 of 5 types (small with ledge, small, medium with ledge, large with ledge, large)
<i>Metal plain matrices including</i>		
Metal matrix bands	1.0930, 1.0932, 1.0933, 1.0935	Premolar plain metal matrices of 1 of 3 shapes: without ledge, bilateral, with one side ledge
	1.0931, 1.1932, 1.1933, 1.1935, 1.1937	Molar plain metal matrices of 1 of 3 shapes: without ledge, bilateral, with one side ledge
	1.380, 1.381,	Rectangular (sequiland) matrix - bands
	1.378, 1.379	T-bands, metal
	1.382, 1.383	Metal strips 50 mm long, 0,06/0,09 mm thick, 6 mm wide
Metal striprolls	1.390, 1.391, 1.392, 1.393	Metal strips 3 m long 6 / 7 mm wide packed in rolls (different packages)
Saddle metal plain matrices	1.301, 1.302, 1.303	Plain matrices with cylinder-shape tubes at the edges of 1 of 3 types
Perforated metal plain matrices	1.331(1), 1.331(2), 1.331(3), 1.331(4), 1.331(5)	Perforated contoured matrices of 1 of 2 types (small, large with ledge) Matrix bands for tartar removal

1.386

Metal sectional matrices

Sectional Contoured Metal Matrices	1.0971, 1.0972, 1.0973, 1.0974, 1.0975, 1.0976,	Matrices of 1 of 6 shapes: small, small with ledge, medium, medium with ledge, large, large with ledge
	1.097,	Matrices of 2 shapes
	1.098,	Matrices of 3 shapes
	1.198, 1.298,	Matrices of 6 shapes with ring 1.099(5)
	1.398,	Matrices of 6 shapes with rings 1.099(5) and 1.299
	1.1972, 1.1973, 1.1976	Small / Large / Medium matrices of 4 various thicknesses

Combined (metal/plastic) matrix bands

Plastic-Metal Combined Matrices	1.034, 1.134	Premolar / Molar plain bilateral half metal / half matrices of 1 shape
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Accessories

Spring matrix retainers, tubular and Tofflemire retainers, forceps for installation of spring matrix retainers

Intended use: dental filling modeling, to retain dental matrices on tooth

Rings	1.022, 1.022c	Ring for perforated matrices
	1.033, 1.033c	Ring for saddle matrices
	1.044, 1.044c	Slot ring for matrices Pony
	1.099(4),	Ring for sectional matrices (tines height – 4 mm)
	1.099(5), 1.099c	Ring for sectional matrices (tines height – 5 mm)
	1.099 A	Ring for sectional matrices (tines height – 6 mm)
	1.099(6),	Ring set – rings 1.099(4)+1.099(5)+1.099(6)
	1.399,	D-ring and M-ring, MD –ring (for installation on distal and medial side of the tooth and on both surfaces)
	1.166, 1.177, 1.167	
	1.166c, 1.177c, 1.167c	
	1.199, 1.199 c	Flat ring for sectional matrices
	1.299, 1.299 c	Delta ring (with double tines for installation of fixing wedges and add-on wedges 1.861)
Springclips	1.002,	Springclip for perforated matrices
	1.003,	Small springclip for saddle matrices
	1.005,	Large springclip for saddle matrices
	1.004	Slot springclip for matrices Pony
	1.009	Springclip for sectional matrices
Tubular matrix retainer with stopper	1.141	Cervical former (retainer) with stopper for cervical matrix system
Tofflemire retainer	1.007	Tofflemire retainer
Forceps	1.099-1,	Forceps for installation of rings
	1.099-3	
	1.099-2	Forceps for installation of rings and

elastic wedges 1.808

Wooden and plastic fixing wedges (transparent and non-transparent)

Intended use: dental filling modeling, to prevent contact between teeth during manipulations of the dentist

Wooden wedges	1.181, 1.182, 1.183, 1.184, 1.185, 1.186, 1.187, 1.080, 1.083, 1.085, 1.281	Anatomically shaped wooden wedges of 1 of 7 types: superthin & short, thin & short (2 types), thin & long, medium & short, medium & long, thick & long Wooden wedges of 2 types Wooden wedges of 4 types Wooden wedges of 6 types Triangle wooden wedges
Elastic wedges	1.801, 1.802, 1.808	Elastic wedges of 1 of 2 types (hard or soft) Elastic wedges of 2 types (hard & soft)
Add-on plastic wedges	1.861	Plastic wedges with holes for installation of fixing rings or springclips
Transparent plastic wedges	1.811, 1.810, 1.820	Thin transparent wedges Thin and medium transparent wedges
Non-transparent plastic wedges	1.841, 1.840	Thin plastic wedges Thin and medium plastic wedges

Polishing Dental Strips with Two Different Abrasive Layers PSh «TOR VM»

according to Technical File 9391-003-49962851-00

Registration Certificate № FCR 2010/07255

Issued on February 03, 2016 by Federal Service on Surveillance in Health Care (ROSZDRAVNADZOR), Russian Federation

Intended use: polishing of dental fillings

Finishing and polishing strips	1.050, 1.051, 1.052, 1.053, 1.054, 1.055	Strips for gross reduction Strips for contouring Strips for polishing Kit for contouring Kit for finishing Universal kit of polishing strips
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Dental Accessories for Operating Field Isolation

according to Technical File 9398-007-49962851-2015

Registration Certificate № RZN 2016/3671

Issued on February 15, 2016 by Federal Service on Surveillance in Health Care (ROSZDRAVNADZOR), Russian Federation

Intended use: isolation of operating field in dentistry

Dental clamps	W9, 9, 212, W2, 2, W2A, 2A, W3, W7, 7, W8A, 8, 12A, 13A, W56, B1, B2, B3, B4, B5	For anteriors and posteriors , 1 pcs
Forceps	3.993	For clamp installation 1 pcs

Clamp organizing board	3.908, 3.909, 3.912	For 8, 9, 12 clamps sterilization and storage
Microcut	1.384, 1.385, 1.389	Holder, saw blades, diamond strips
Contact former	1.941-1.1945	For matrix adaptation
Tongue and cheek retractor	1.019, 1.119	For tooth isolation
Cotton roll holder	1.010	To keep cotton rolls

Signature
Oleg Mikhalev
CEO
TOR VM


