

# DECLARATION OF CONFORMITY

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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

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)

Date of the first CE mark : August 10, 2005

Date of the first lot : October 25, 2010

Moscow, November 21, 2016



A handwritten signature in blue ink, consisting of several loops and a long vertical stroke.

Dr. Oleg Mikhalev  
CEO,  
TOR VM