ООО ЭргоПродакшн
199106 Санкт-петербург, Шкиперский проток, 14, к. 39, лит. Н
ErgoProduction LLC
Liter N, building 14, corp. 39, Shkiperskiy protok, 199106 St. Petersburg, Russia

Document 18 Dec 2017

DECLARATION OF CONFORMITY

Manufacturer: ErgoProduction LLC
Address: Liter N, building 14, corp. 39,
Shkiperskiy protok, 199106 St. Petersburg
Russia

Product Name	*Product Numbers (package)*
HISTOMIX®	247/NS. (5 x 1 kg) ; 247/NS./1 (1 kg); 247/NS./20 (20 kg); 247/NS./25 (25 kg)
HISTOMIX® EXTRA	10342/NS.(5 x 1 kg); 10342/NS./1 (1 kg); 10342/NS./20 (20 kg); 10342/NS./25 (25 kg)
Mr.Wax®	01-006/NS.(5 x 1 kg); 01-006/NS./1 (1 kg); 01-006/NS./20 (20 kg); 01-006/NS./25 (25 kg)
Mr.Wax® EXTRA	01-007/NS.(5 x 1 kg); 01-007/NS./1 (1 kg); 01-007/NS./20 (20 kg); 01-007/NS./25 (25 kg)

IVD Medical Devices:
WE, the manufacturer, declare and ensure with sole responsibility that products listed above meet the applicable requirements of the European *In Vitro* Diagnostic Directive 98/79/EC.

Device Classification: *Article 9, section 1, "Other" IVD*

Conformity Assessment Route: This declaration is based on conformity assessment procedure of Directive 98/79/EC Annex III.

EC Authorized Representative: Medical Device Safety Service GmbH (MDSS)
Schiffgraben 41
30175 Hannover
Germany

Applied Standards:
EN ISO 13485
EN ISO 14971
EN ISO 18113-1
EN ISO 18113-2

Signature of Company Representative:

Name: R. Anosov
Title: LLC Ergoproduction Managing Director
Date: December 18, 2017