

# Certificate of CE-Registration



MDSS

Medical Device Safety Service

This is to certify that, in accordance with the *In Vitro* Diagnostic Medical Device Directive 98/79/EC, Medical Device Safety Service GmbH (MDSS) agrees to perform all duties and responsibilities as the Authorized Representative for:

**ErgoProduction Limited Liability Company**  
**Shkipersky protok 14-39 lit. N**  
**St. Petersburg 199106**  
**RUSSIA**

as stipulated and demanded by the aforementioned Directive. The European Databank on Medical Devices (EUDAMED) is established as of May 1, 2011. The German Competent Authority is notified of the manufacturer's *in vitro* diagnostic medical devices and has allocated registration numbers shown in:

**Annex A dated March 16, 2018**

The Manufacturer has provided MDSS with the appropriate Declaration(s) of Conformity confirming that the *in vitro* diagnostic medical devices fulfill the applicable requirements of Directive 98/79/EC. In compliance with German law, a safety officer has been appointed for Germany.

2018-03-16



Ludger Möller  
President  
MDSS GmbH

Annex A: March 16, 2018

Manufacturer: ErgoProduction BioVitrum

REF	Device Names (notified)	Optional information	Nomenclature	Code (notified)	Description (notified)	Class (notified)	EC Certificate No. & Expiry (notified)	German Registration Number
247/NS. 247/NS./1 247/NS./20 247/NS./25	HISTOMIX®	(5x1 kg) (1 kg) (20 kg) (25 kg)	EDMA	13 07 01 04	Embedding media (Histology/Cytology)	"Other"	N/A	DE/CA09/0170/E31/IVD/001
10342/NS. 10342/NS./1 10342/NS./20 10342/NS./25	HISTOMIX® EXTRA	(5x1 kg) (1 kg) (20 kg) (25 kg)	EDMA	13 07 01 04	Embedding media (Histology/Cytology)	"Other"	N/A	DE/CA09/0170/E31/IVD/001
01-006/NS. 01-006/NS./1 01-006/NS./20 01-006/NS./25	Mr. Wax®	(5x1 kg) (1 kg) (20 kg) (25 kg)	EDMA	13 07 01 04	Embedding media (Histology/Cytology)	"Other"	N/A	DE/CA09/0170/E31/IVD/001
01-007/NS. 01-007/NS./1 01-007/NS./20 01-007/NS./25	Mr. Wax® EXTRA	(5x1 kg) (1 kg) (20 kg) (25 kg)	EDMA	13 07 01 04	Embedding media (Histology/Cytology)	"Other"	N/A	DE/CA09/0170/E31/IVD/001