



**"Association of Medicine and Analytics" Company Limited**

**"AMA" Co Ltd**

17 line of Vasilievsky Island, 4-6, 199034, Saint-Petersburg, Russian Federation

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Web: [www.amamed.ru](http://www.amamed.ru)

## Declaration of Conformity

PRODUCT IDENTIFICATION	
Product name	Model
Helicobacter pylori AMA RAPID UREASE TEST (AMA RUT)	AMA RUT 1 AMA RUT 3 AMA RUT 10 AMA RUT 21 AMA RUT Expert AMA RUT Pro AMA RUT Reader

MANUFACTURER		
Name of the company	Address	Representative
Association of Medicine and Analytics Company Limited (AMA Co., Ltd.)	17 line of Vasilievsky Island, 4-6, 199034, Saint-Petersburg, Russia	M. Evdokimova

AUTHORIZED REPRESENTATIVE		
Name of the company	Address	Telephone/email
Emergo Europe	Prinsessegracht 20 2514 AP The Hague The Netherlands	Tel: (31) (0) 70 345-8570 Fax: (31) (0) 70 346-7299 Email: <a href="mailto:europe@emergogroup.com">europe@emergogroup.com</a>

CONFORMITY ASSESSMENT		
Device classification	Route to compliance	Standards applied
IVD-Other	Annex III of IVDD 98/79/EC Council Directive	ISO 9001:2012 EN ISO 13485:2012 EN ISO 14971:2012 EN 61010-1:2011 EN 61010-2-101:2002 EN 61326-1:2013 EN 62366:2008 EN ISO 15223-1:2012 EN 62304, Edition: 2005-04 Directive 98/79/EC

Association of Medicine and Analytics Co., Ltd. declares that above mentioned product meets the provision of the Council Directive 98/79/EC for in vitro diagnostic medical devices.

**NAME / TITLE:** President (CEO) / Marina Dmitrienko

**SIGNATURE:**

**DATE:** 2018-11-04

