

EU Declaration of Conformity

We Hamilton Bonaduz AG, CH-7402 Bonaduz/Switzerland confirm that the following product

Product name AltoStar® Automation System AM16

Based on Microlab STARlet IVD

PN 806160

SN

meets the following EU directives (including all applicable amendments):



IVD Directive

98/79/EU

RoHS II

2011/65/EU

Applied company quality management systems

EN ISO 9001

EN ISO 13485

Certification Body

TÜV Rheinland LGA Products GmbH

Am Grauen Stein 29

D-51105 Köln-Poll, Germany

Applied standards:

Safety:

EN 61010-1 (2010)

EN 61010-2-010 (2014)

EN 61010-2-101 (2015)

EN 60825-1 (2015)

EMC:

Emission

EN 61326-1 (2013) class B

EN 61326-2-6 (2013)

Immunity

EN 61326-1 (2013) Basic environment

EN 61326-2-6 (2013)

Risk Management:

ISO 14971 (2012)

Labeling

ISO 15223-1 (2012)

Additional Information:



Canada, USA

Certificate
No. U8 98577

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Authorize department for technical documents:

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