

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

P/N 806160

S/N

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 61010-2-081	(2015)
		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

CAN/CSA-C22.2 No. 61010-1

& -2-010 & -2-081 & -2-101

UL Std. No. 61010-1, 3rd Edition

FCC, Part 15, class A

Authorize department for technical documents:

HAMILTON Quality Department Robotics

Hamilton Bonaduz AG

Andreas Wieland
CEO

Bonaduz, 30.6.2017