DIAGNOSTICS

Your Key To Reliable Quality Controls

DECLARATION OF CONFORMITY

European Union *In Vitro* Diagnostic Directive 98/79/EC (IVDD)

Date of Issue:	18 April 2019
Certificate Ref.:	These products are self-declared for compliance to Annex III of the IVDD. These products do not claim any analytes listed in Annex II List A or B.
Directive:	98/79/EC IVD Directive of 27 October 1998

Conforming Products:

Catalog Number	Product Description	EDMA Classification	GMDN Code
	More RAP/TAC/CSA Control	12.50.01.02	55235
280-1	Control 1 4 x 4 mL		
280-2	Control 2 4 x 4 mL		
280-3	Control 3 4 x 4 mL		

Manufacturer:	More Diagnostics Inc., 2020 11th Street, Los Osos, CA 93402, USA
Authorized Representative:	B•R•A•H•M•S GmbH, Neuendorfstraße 25, D-16761 Hennigsdorf, Germany
Notified Body:	Intertek Testing Services NA, Inc., Lowell, MA, USA
Harmonized Standards Referenced:	• EN 13612:2002 • EN 13640:2002 • EN 13641:2002 • EN ISO 14971:2012 • EN ISO 18113-1:2011 • EN ISO 18113-2:2011 • EN ISO 13485:2016
Other regulations/ standards by which product is regulated:	• 21 CFR Parts 820, Quality System Regulations • EN ISO 15223-1:2012, Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements • ANSI Z400.1:2010 Material safety data sheet preparation

More Diagnostics Inc. Quality Management System is certified to EN ISO 13485:2016 by Intertek Testing Services NA, Inc., Lowell, MA, USA. Certificate # 0084556.

We hereby certify that as of the date of this declaration, the products described above conform with the provisions of Council Directive 98/79/EC IVD Directive of 27 October 1998 related to *in-vitro* diagnostic devices. All supporting documentation is retained at More Diagnostics Inc.

Signature: _____ Date: 4/18/2019

Endre D. Vargha, CEO/President, More Diagnostics Inc.

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