

Declaration of Conformity

LEGAL MANUFACTURER:	Siemens Healthcare Diagnostics Inc. 511 Benedict Avenue Tarrytown, New York 10591-5097 USA
PLACE OF MANUFACTURE:	Bionostics Inc. 7 Jackson Road Devens, MA 01434-4204 U.S.A.
EU AUTHORIZED REPRESENTATIVE	Siemens Healthcare Diagnostics Manufacturing Ltd. Chapel Lane Swords, Co. Dublin, Ireland
PRODUCT:	RapidQC® Plus, RapidQC® Complete, RapidQC® Hct, High G/L & CO-ox Slope, CVM
PRODUCT LIST:	See attachment 1
CLASSIFICATION:	Self Declaration
CONFORMITY ASSESSMENT ROUTE:	ANNEX III Applied
STANDARDS APPLIED:	<u>EN ISO 14971:2012</u> – Medical Devices - Application of Risk Management to Medical Devices <u>ISO 13485:2016</u> – Medical Devices - Quality Management Systems for Medical Devices <u>ISO 15223-1:2012</u> - Symbols to be Used with Medical Device Labels, Labeling and Information to be Supplied Part 1: General Requirements <u>ISO 15223-2:2010</u> – Symbols to be Used with Medical Device Labels, Labeling and Information to be Supplied Part 2: System Development, Selection and Validation <u>EN ISO 18113-1:2011</u> – In Vitro Diagnostic Medical Devices – Information Supplied by the Manufacturer (Labeling) – Part 1, Terms, definitions and general requirements <u>EN ISO 18113-2:2011</u> – in Vitro Diagnostic Medical Devices – Information Supplied by the manufacturer (Labeling) – Part 2: In vitro diagnostic reagents for professional use <u>EN ISO 17511:2003</u> – In Vitro Diagnostic Medical Devices – Measurement of quantities in biological samples – metrological traceability of values assigned to calibrators and control materials

**Siemens Healthcare Diagnostics Inc.
Norwood, Massachusetts, USA**

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We herewith declare that the above-mentioned product(s) meet the provisions of the Council Directive 98/79/EC for in vitro diagnostic medical devices. The Manufacturer retains all supporting documentation.

Attachment 1

SMN	REF (BAN)	Product Code	Description
10323692	06057533	478941000	Rapid QC Plus Level 1
10341140	03867186	478942000	Rapid QC Plus Level 2
10325104	06750158	478943000	Rapid QC Plus Level 3
10309925	02017464	108860	Rapid QC Complete Level 1
10309926	07519905	108868	Rapid QC Complete Level 2
10309927	07182730	108869	Rapid QC Complete Level 3
10311387	09733092	570097	High G/L
10311392	04116087	570405	Rapid QC Hct Level A
10311393	06081574	570406	Rapid QC Hct Level B
10325087	02299680	473120000	CO-ox Slope
10316535	02147872	116189	CVM Calibration Verification Material

End of list

Jim Novesteras
 Regulatory Affairs Associate

Date