

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:

EN ISO 14971:2012 – Medical Devices - Application of Risk Management to Medical Devices
ISO 13485:2016 – Medical Devices - Quality Management Systems for Medical Devices
ISO 15223-1:2012 - Symbols to be Used with Medical Device Labels, Labeling and Information to be Supplied Part 1: General Requirements
ISO 15223-2:2010 – Symbols to be Used with Medical Device Labels, Labeling and Information to be Supplied Part 2: System Development, Selection and Validation

EN ISO 18113-1:2011 – In Vitro Diagnostic Medical Devices – Information Supplied by the Manufacturer (Labeling) – Part 1, Terms, definitions and general requirements

EN ISO 18113-2:2011 – in Vitro Diagnostic Medical Devices – Information Supplied by the manufacturer (Labeling) – Part 2: In vitro diagnostic reagents for professional use

EN ISO 17511:2003 – 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

Novasteras Jim

Digitally signed by Novasteras Jim
DN: serialNumber=Z003W8MR, givenName=Jim,
sn=Novasteras, o=Siemens, cn=Novasteras Jim
Date: 2019.03.12 20:00:02 -04'00'

Jim Novasteras
Regulatory Affairs Associate

Date

Siemens Healthcare Diagnostics Inc.
Norwood, Massachusetts, USA

