DECLARATION OF CONFORMITY

RAPIDChem Instruments, Reagents, Sensors and Consumables

SIEMENS Healthineers

LEGAL MANUFACTURER	SIEMENS Healthcare Diagnostics Inc. 511 Benedict Avenue Tarrytown, New York 10591 USA
PLACE OF MANUFACTURER	MEDICA Corporation 5 Oak Park Drive Bedford, MA 01730 USA
EU AUTHORIZED REPRESENTATIVE	SIEMENS Healthcare Diagnostics Manufacturing Ltd. Chapel Lane Swords, Co. Dublin IRELAND
PRODUCT	**Rapidchem Instrument, Reagents, Sensors and Consumables**
PRODUCT CATEGORY	See **TABLE I**
CLASSIFICATION	Self-Declaration
CONFORMITY ASSESSMENT ROUTE	Annex III Applied

STANDARDS APPLIED

ISO 13485:2016	MEDICAL DEVICES - Quality Management System Requirements - Requirements for Regulatory Purposes
EN ISO 14971:2019	MEDICAL DEVICES - Application of Risk Management to Medical Devices
IEC 61010-1:2010	Safety requirements for electrical equipment for measurement, control, and laboratory use. Part 2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes BS EN 591:2001 Instructions for Use for in Vitro Diagnostic Instruments for Professional Use
ISO 13612:2002	Performance Evaluation of In Vitro Diagnostic Medical Devices
EN 13640:2002	Stability Testing of *In Vitro* Diagnostic Medical Devices
IEC 61326-1:2020	Electrical Equipment for Measurement Control and Laboratory Use, PART 1: General Requirements – Electromagnetic Compatibility

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STANDARDS APPLIED (continued)

EN IEC 63000:2018	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances
EN 591:2001	Instructions for Use for In Vitro Diagnostic Instruments for Professional Use
EN 980:2003	Graphical Symbols for Use in the Labeling of Medical Devices
EN 375:2001	Information supplied by the Manufacturer with In Vitro Diagnostic Reagents for Professional Use

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We herewith declare that the below-mentioned product(s) meet the provisions of the Council Directive 98/79/EC and elements specified in the RoHS Directive 2011/65/EU as amended by Amendment 2015/863/EU for *in vitro* diagnostic medical devices therefore have fulfilled all requirements for applying the CE mark to the *in vitro* Medical Devices(s). The Manufacturer retains all supporting documentation.

ATTACHMENT I

SMN	REF (BAN)	PRODUCT CODE	DESCRIPTION
10308995	00938058	----	Urine Diluent Solution
10309048	02970609	----	RAPIDChem Reagent Module Na/K/Cl •
10337014	06090867	----	RAPIDChem 744 ∗Δ
10284318	08775212	21	RAPIDChem 744 ∗Δ
10324039	06254738	22	RAPIDChem 744 ∗Δ
10324147	06311049	23	RAPIDChem 744 ∗Δ
10337480	06489859	24	RAPIDChem 744 ∗Δ
10340460	09399834	25	RAPIDChem 744 ∗Δ
10326702	07638955	26	RAPIDChem 744 ∗Δ
10309090	05679131	27	RAPIDChem 744 ∗Δ
10316969	02399588	28	RAPIDChem 744 ∗Δ
10339834	08720949	29	RAPIDChem 744 ∗Δ
10309086	05453710	30	RAPIDChem Sensor Module
10309075	04473866	31	RAPIDChem Sodium Electrode
10309082	04955798	32	RAPIDChem Potassium Electrode
10309034	02283180	33	RAPIDChem Reference Electrode
10308989	00661439	34	RAPIDChem Chloride Electrode
10309011	01331777	36	RAPIDChem 744/754 Analyzer Daily Cleaning Solutions
10334914	04012036	37	RAPIDChem 754 ∗Δ
10329069	08915766	38	RAPIDChem 754 ∗Δ
10317088	02456344	39	RAPIDChem 754 ∗Δ
10340828	9772640	40	RAPIDChem 754 ∗Δ
10334913	04011641	41	RAPIDChem 754 ∗Δ
10327443	08027569	42	RAPIDChem 754 ∗Δ
10309672	08464780	43	RAPIDChem 754 ∗Δ
10318482	03191840	44	RAPIDChem Sensor Module Li •
10308981	00583772	45	Lithium Electrode
10309093	05840552	46	RAPIDChem Reagent Module Na/K/Li •
10309089	05610166	47	Daily Cleaning Solution Kit

END OF LIST

Siemens Healthcare Diagnostics, Inc.

Electronically signed by: Robert Zinck
Reason: I am approving this document
Date: Jul 19, 2021 19:02 EDT

Bobby Zinck
Manager, Regulatory Affairs

Jul 19, 2021
Date