

Declaration of Conformity

LEGAL MANUFACTURER: Siemens Healthcare Diagnostics Inc.
Tarrytown, NY 10591-5097
USA

PLACE OF MANUFACTURE: Kimball Electronics Poland Sp z 0.0
ul. Poznanska 1/C
tarnowo podgorne Poland 62080

PRODUCT: Visual & Instrument Read strips


PRODUCT CATEGORY: See Attachment 1

CLASSIFICATION: Self Declaration

CONFORMITY ASSESSMENT ROUTE: Annex III Applied

STANDARDS APPLIED: ISO 13485:2003 – Quality System for Medical Devices
IVDD 98/79/EC:1998
EN 13612:2002 – Performance Evaluation of In Vitro Medical Devices
EN 13640:2002 – Stability Testing of In Vitro Diagnostic Reagents
EN ISO 14971:2012 – Medical Devices- Application of Risk Management to 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: Symbol Development, Selection, and Validation
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
EN ISO 18113-1:2011 – In Vitro Diagnostic Medical Devices – Information Supplied by the Manufacturer (Labelling) – Part 1: Terms, Definitions and General Requirements
EN ISO 18113-2:2011 - In Vitro Diagnostic Medical Devices – Information Supplied by the Manufacturer (Labelling) – Part 2: In Vitro Diagnostics Reagents for Professional Use

Siemens Healthcare Diagnostics Inc.
Norwood, Massachusetts, USA

 21 Apr 2014

Susan Tibedo Date
Sr. Manager – Regulatory - POC

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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
REF (BAN) /SMN	Product Code	Description
03783489/103 19565	A2292C52	Multistix 10 SG Latin (25)
05328339/103 22360	A2300A29	Multistix 10 SG Nordic
03536597/103 19133	A2300C51	Multistix 10 SG Europe
00718686/103 13959	A2300C52	Multistix 10 SG Latin (100)
04200746/103 20335	A2304C51	Multistix 8 SG Europe (50)
05258055/103 22217	A2304D29	Multistix 8 SG Nordic (100)
08646323/103 28579	A2087A52	Microalbustix
09159477/103 28660	A2289A52	Multistix 8 SG Latin
01211267/103 14818	A2305D29	Multistix 7 Nordic
07900226/103 27186	A2740C51	N-Multistix SG Europe
07771019/103 26937	A2740C52	N-Multistix SG Latin
08259974/103 27901	A2810C51	Labstix Europe
02827164/103 17784	A2810C52	Labstix Latin
04581138/103 20975	A2810F29	Labstix Nordic
05205326/103 22126	A2857C51	Uristix Europe
01037046/103 14513	A2857C52	Uristix Latin
04010718/103 00006	A2857E29	Uristix Nordic
06562467/103 24743	A2877C51	Hema-Combistix Europe

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05798300/103 23220	A2330B50	Multistix 10 Visual
04960872/103 21658	A2087B51	Microalbustix
04624902/103 21054	A2283J01	Multistix GP UK/Spain
03570159/103 19183	A2291C18	Multistix 10 SG Germany
02156642/103 16556	A2300B21	Multistix 10 SG
03390851/103 18865	A2300C40	Multistix 10 SG
06565954/103 24751	A2308A52	Multistix 5
07500392/103 26466	A2308C29	Multistix 5
03242542/103 18564	A2308C51	Multistix 5
08955414/103 29106	A2741B51	Multistix SG
04240977/103 20395	A2743J01	Labstix SG
07571427/103 26594	A2815C51	N-Labstix
00828708/103 14160	A2820C51	Multistix
05441720/103 22559	A2825C18	N-Neostix
01526748/103 15394	A2300D18	Multistix 10 SG
		End of List

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