

Declaration of Conformity

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

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

PRODUCT: See Attachment 1

PRODUCT CATEGORY: Self-Test Products

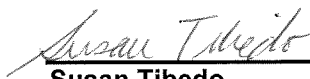
CLASSIFICATION: Annex III

CONFORMITY ASSESSMENT ROUTE: Annex IV 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

NOTIFIED BODY: Lloyd's Register Quality Assurance Ltd.
Identification No. 0088

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.

REF (BAN) /SMN		Attachment 1
Item Code		Description
08408406/1032 8167	A2286D34	Uritest® (French / Italian)
07639781/1032 6704	A2010C34	Uritest 2® (French / Italian)
02597428/1031 7353	A2816C51	Hemastix® (English / French/ German / Danish)
01152317/1031 4716	A2816C52	Hemastix® (Italian / Spanish / Portuguese / Greek)
06546712/1032 4683	A2816E29	Hemastix® (Nordic)
02614217/1031 7384	A2872C51	Albustix® (English / French/ German / Danish)
06184853/1032 3904	A2872C52	Albustix® (Italian / Spanish / Portuguese / Greek)
03348227/1031 8774	A2872E29	Albustix® (Nordic)

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