SIEMENS

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:	**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

Susan Tibedo 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	**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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Norwood, Massachusetts, USA

Susan Tibedo 21 Apr 2014

Susan Tibedo **Date**
Sr. Manager – Regulatory - POC