

Declaration of Conformity

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|-------------------------------------|--|
| LEGAL MANUFACTURER: | Siemens Healthcare Diagnostics Inc. 511 Benedict Avenue Tarrytown, New York 10591-5097 USA |
| PLACE OF MANUFACTURE: | Fisher Diagnostics, A division of Fisher Scientific Company LLC, A part of Thermo Fisher Scientific Inc., 8365 Valley Pike, Middletown, VA, 22645-0307, United States of America. |
| EU AUTHORIZED REPRESENTATIVE | Siemens Healthcare Diagnostics Manufacturing Ltd. Chapel Lane Swords, Co. Dublin, Ireland |
| PRODUCT: | DCA Systems Microalbumin / Creatinine Low & High Control Kit |
| PRODUCT CATEGORY: | See attachment 1 |
| CLASSIFICATION: | Self Declaration |
| CONFORMITY ASSESSMENT ROUTE: | ANNEX III Applied |
| STANDARDS APPLIED: | <u>ISO 13485:2003</u> ; EN ISO 13485:2012 – Medical Devices - Quality Management Systems for Medical Devices <u>EN ISO 14971:2012</u> – Medical Devices - Application of Risk Management to Medical Devices <u>EN ISO 18113-1:2011</u> – In vitro diagnostic medical devices - Information Supplied by the Manufacturer (Labeling) Part 1: Terms, definitions and general requirements <u>EN ISO 18113-2:2011</u> – In vitro diagnostic medical devices - Information Supplied by the Manufacturer (labeling) (Part 2): In vitro diagnostic reagents for professional use <u>EN ISO 18113-3:2011</u> – In vitro diagnostic medical devices - Information Supplied by the Manufacturer (labeling) Part 3): In vitro diagnostic instruments for professional use <u>ISO 15223-1:2012</u> – Symbols to be used with medical device labels, labeling and information to be supplied- Part1:General requirements <u>ISO 15223-2:2010</u> – Symbols to be used with medical device labels, labeling and information to be supplied- Part 2: Symbol development, selection and validation |

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 |
|----------|-----------|--------------|--|
| 10325406 | 06916803 | 6012A | Microalbumin / Creatinine Low & High Control Kit |

End of List

Jim Novesteras
Regulatory Affairs Associate

Date

Siemens Healthcare Diagnostics Inc.
Norwood, Massachusetts, USA