Declaration of Conformity

LEGAL MANUFACTURER:	**Siemens Healthcare Diagnostics Inc. Tarrytown, New York 10591-5097 USA**
PLACE OF MANUFACTURE:	**ALFA Scientific Designs, Inc. 13200 Gregg St. Poway, CA 92064-7121 U.S.A.**
EU AUTHORIZED REPRESENTATIVE:	**Siemens Healthcare Diagnostics Manufacturing Ltd. Chapel Lane Swords, Co. Dublin, Ireland**
PRODUCT:	**Clinitest hCG Pregnancy Test**
PRODUCT CATEGORY:	**See attachment 1**
CLASSIFICATION:	**Self Declaration**
CONFORMITY ASSESSMENT ROUTE:	**ANNEX III Applied**
STANDARDS APPLIED:	**ISO 13485:2016 - Medical Devices – Quality Management Systems Requirements for regulatory purposes ISO 14971:2012 - Medical Devices – Application of risk management to medical devices ISO 15223-1:2012 – Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: Terms, definitions and general requirements. ISO 15223-2:2010- Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 2 Symbol development, selection and validation EN ISO 18113-1:2011 – In vitro Diagnostic Medical Devices – Information Supplied by the Manufacturer (labeling) – Part 1: Terms, definitions and general requirements. EN ISO 18113-2:2011 - In vitro Diagnostic Medical Devices – Information Supplied by the Manufacturer (labeling) –Part 2 Invitro diagnostic reagentes for professional use EN 13612:2002/AC:2002 – Performance evaluation of in vitro diagnostic medical devices EN13640:2002- Stability testing of in vitro diagnostic reagents ISO 17511:2003 – In vitro diagnostic medical devices – Measurement of quantities in biological samples – Metrological traceability of values assigned to calibrators and control materials**

SIEMENS Healthineers

Declaration of Conformity

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
10310618	06484105	1760	Clinitest hCG

End of List

Novesteras Jim

Digitally signed by Novesteras Jim
DN: serialNumber=Z003W8MR, givenName=Jim, sn=Novesteras, o=Siemens, cn=Novesteras Jim
Date: 2019.03.04 16:59:47 -05'00'

Jim Novesteras
Regulatory Affairs Associate

Date