SIEMENS

Declaration of Conformity

LEGAL MANUFACTURER:	**Siemens Healthcare Diagnostics Inc. 511 Benedict Avenue Tarrytown, New York 10591-5097 USA**
PLACE OF MANUFACTURE:	**Splitvision Design AB Hudiksvallsgatan 8 113 30 Stockholm Sweden**
EU AUTHORIZED REPRESENTATIVE	**Siemens Healthcare Diagnostics Ltd. Sir William Siemens SQ. Frimley, Camberley, UK GU16 8QD**
PRODUCT:	**Xprecia Stride™ Accessory Kit**
PRODUCT CATEGORY:	**See Attachment 1**
CLASSIFICATION:	**Self-Declaration**
CONFORMITY ASSESSMENT ROUTE:	**Annex III Applied**

EN ISO 13485:2003 – Medical devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971:2012 – Medical devices – Application of risk management to medical devices
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 diagnostic reagents for professional use
EN ISO 18113-3:2011 – In vitro diagnostic medical devices – Information supplied by the manufacturer (labelling) – Part 3: In vitro diagnostic instruments for professional use
BS EN 980:2008 – Symbols for use in the labelling of medical devices
IEC 62321, Ed.1:2008 – Procedures for the determination of levels of six regulated substances (Lead, Mercury, Cadmium, Hexavalent Chromium, Polybrominated Biphenyls, Polybrominated Diphenyl Ethers) in electrotechnical products
(EC) 1907/2006 – Regulation (EC) 1907/2006 of the European Parliament and the Council

Siemens Healthcare Diagnostics Inc.
Norwood, Massachusetts, USA

P.B. Patel 2017-01-17

Priyank Patel Date:
Technical Specialist, Regulatory Affairs - POC

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concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH)
EN 62304:2006 – Medical device software – Software life-cycle processes
EN 62366:2008 – Medical devices – Application of usability engineering to medical devices
ISTA Procedure 3A - Packaged-Products for Parcel Delivery System Shipments 70kg (150 lb) or Less (standard, small, flat or elongated)

We herewith declare that the above-mentioned product(s) meet the provisions of the Council Directive 98/79/EC and elements specified in RoHS Directive 2011/65/EU for in vitro diagnostic medical devices. The Manufacturer retains all supporting documentation.

Attachment 1		
REF (BAN)/SMN	**Product Code**	**Description**
10714617	10714617	Xprecia Stride™ Accessory Kit

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Priyank Patel Date:
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