FUJIFILM

FUJIFILM Corporation
26-30, NISHIAZABU 2-CHOME, MINATO-KU
TOKYO 106-8620, JAPAN

CÔNG TY TRÁCH NHIỆM HỮU HẠN FUJIFILM VIỆT NAM
THÀNH PHỐ HỒ CHÍ MINH

Declaration of Conformity

08 - CEI - 265 - D

Manufacturer:	FUJIFILM Corporation
Address:	26-30, Nishiazabu 2-chome, Minatoku, TOKYO 106-8620, JAPAN
European Representative:	FUJIFILM Europe GmbH
Address:	HEESENSTRASSE 31, 40549 DÜSSELDORF, GERMANY
Product:	FUJI DRI-CHEM SLIDE HDL-C-P IIID
GMDN Code	30169
EDMA Code	11.02.01.15
Start of CE Marking:	Lot No.193509
Classification:	The device is not referred in Article 9 (2) and (3).
Conformity Assessment Route:	Annex III without Section 6

We herewith declare that the above mentioned product meets the provisions of the following EC Council Directive.

Directive:

COUNCIL DIRECTIVE 98/79/EC of 27 October 1998 on in vitro diagnostic medical devices (IVDD 98/79/EC)

Standards:

EN ISO13485:2012 Medical devices - Quality management systems - Requirements for regulatory purpose

EN ISO 14971:2012 Medical devices - Application of risk management to medical devices

EN 13612: 2002 Performance evaluation of in vitro diagnostic medical devices

EN 13640:2002 Stability testing of in vitro diagnostic reagents

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 15223-1:2012 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements

Place: JAPAN

Date: 2014-10-01

Naotake Mitsumori

Naotake Mitsumori
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Quality Assurance and Regulatory Affairs Division
Medical Systems Business Division
FUJIFILM Corporation