

FUJIFILM



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

Declaration of Conformity

05 - CEI - 150 - F

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 NH₃-W II**
GMDN Code 30185
EDMA Code 11.03.01.01
Start of CE Marking: Lot No.210306
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

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Senior Manager,
Quality Assurance and Regulatory Affairs Division
Medical Systems Business Division
FUJIFILM Corporation