PerkinElmer

Manufacturer's name and address
Wallac Oy
Mustionkatu 6
FI-20750 Turku
Finland

DECLARATION OF CONFORMITY FOR CE-MARKING

Name of the device(s)
DELFIA® Wash Concentrate

1244-114

4010-0010

B117-100

3014-0010

We, Wallac Oy, hereby declare that the device(s) mentioned above comply with
European 98/79/EC In Vitro Diagnostic Medical device directive

The product(s) bears the CE mark indicating conformity with the provisions of these directives.

The product(s) are classified as follows according to the in vitro diagnostic medical devices 98/79/EC:
Other device (all devices except Annex II and self testing devices)

Conformity Assessment Procedure:
Self-declaration, Annex III, 98/79/EC

Global Medical Device Nomenclature (GMDN) code for the device
58236

Date and place of issue
31 October 2012, Turku, Finland

Name, position and signature of authorized person

Tuija Halonen
Quality Manager, Reagents

PerkinElmer

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Harmonized Standards used for conformity assessment of compliance

EN ISO 13485	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2003)
EN 13612	Performance evaluation of in vitro diagnostic medical devices
EN 13640	Stability testing of in vitro diagnostic reagents
EN 13641	Elimination or reduction of risk of infection related to in vitro diagnostic reagents
EN 13975	Sampling procedures used for acceptance testing of in vitro diagnostic medical devices - Statistical aspects
EN ISO 14971	Medical devices - Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01)
EN ISO 17511	In vitro diagnostic medical devices - Measurement of quantities in biological samples - Metrological traceability of values assigned to calibrators and control materials (ISO 17511:2003)
EN ISO 18113-1	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements (ISO 18113-1:2009)
EN ISO 18113-2	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use (ISO 18113-2:2009)
EN ISO 15223-1	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements (ISO 15223-1:2012)