ThermoFisher SCIENTIFIC

DECLARATION of CONFORMITY

For IVD - CE Marking

Product: Immunohistology accessory reagents: Mounting media; Stain Solutions; Other Histology / Cytology Reagents.

Description, Product code, Lot number, Expiration date: See label on medical device.

Intended use: In-vitro diagnostic (IVD) medical device.

Notification to Competent Authorities: These devices have been registered with the Medical and Healthcare products Regulatory Agency under the EDMA classification codes 13 - 07 - 01 - 06 - 00; 13 - 07 - 01 - 08 - 00; 13 - 07 - 01 - 90 - 00, "Histology / Cytology Reagents". All other national competent authorities have been notified accordingly.

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Lab Vision Corporation declares, under its sole responsibility, that the product(s) to which this Declaration relates complies with the Standard(s) or Normative Documents detailed below and follows the provisions of the Directives stated.

This product shall be stored and used in applications for which it is manufactured in accordance with Professional Practices, relevant Standard(s) and Lab Vision Corporation's instruction.

EC Directive applicable *Directive* **98/79/EC** *of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices,* OJ, 1998, No L 331. *Article 1, procedure referred to in Annex III.*

Standard(s)
ISO 9001:2008 *Quality management systems - Requirements.*
ISO 13485:2003 *Quality systems - Medical devices - Particular requirements for the application of ISO 9001.*
ISO 14971:2007 *Medical devices - Application of risk management to medical devices.*
BS EN ISO 14971:2009 *Medical devices - Application of risk management to medical devices.*
EN 13640:2002 *Stability testing on in vitro diagnostic reagents.*
BS EN ISO 18113-2:2009 *In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling)- In vitro diagnostic reagents for professional use (ISO 18113-2:2009).*
EN 980:2008 *Symbols for use in the labelling of medical devices.*
UK's MDA:1998 *The Medical Devices Vigilance System - European Commission Guidelines.*

Place and date: Fremont, November 14, 2011

Signature

Name: Karen Lee, *Lab Vision Corp.*
Regulatory Affairs Specialist

Digitally signed by Plămădeală Inga
Date: 2023.05.11 05:29:41 EEST
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