Inova Diagnostics
A Werfen Company

DECLARATION OF CONFORMITY
NOVA View®

Unique Device Identifier (UDI) -Primary DI
08426950631972

Manufacturer:
Inova Diagnostics, Incorporated
9900 Old Grove Road
San Diego, California 92131-1638, USA

EU Authorized Representative:
Medical Technology Promedt Consulting GmbH
Altenhofstrasse 80, D-66386
St. Ingbert, Germany

Inova Diagnostics, Inc. hereby declares that the product(s) listed below conform to the European Union directive and standards identified in this declaration. This statement of conformity is valid in connection with the release document for the respective serial numbers/batch of the produced devices.

EDMA code: 22 03 04- Batch, High throughput I.A. system
GMDN code: No term available

EU Directive:
98/79/EC on *in vitro* diagnostic medical devices - Annex I and III
Non-List A/ Non-List B of Annex II and not for self testing
RoHS2 Directive 2011/65/EU

Standard(s):
ISO 13485:2003– Medical Devices – Quality management systems
ISO 14971:2007 – Medical Devices – Application of risk management to medical devices
ISO 18113-1:2009 – In vitro diagnostic medical devices –Information supplied by manufacturer, (labelling) Terms, definitions, general requirements
ISO 18113-3:2009 – In vitro diagnostic medical devices –Information supplied by manufacturer (labelling) In vitro diagnostic instruments for professional use.
ISO 15223-1:2012– Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
EN 61326-1:2006 –Electrical equipment for measurement, control and laboratory use – EMC requirements, Part1 – General requirements
EN 61326-2-6:2006 – Electrical equipment for measurement, control and laboratory use - EMC requirements -- Part 2-2: Particular requirements - In vitro diagnostic (IVD) medical equipment
IEC 61010-2-101:2002/EN 61010-2-101:2002 - - Safety requirement for electrical equipment for measurement, control, and laboratory use – Part 2:101 - Particular requirements for in vitro diagnostic (IVD) medical equipment.
IEC 61010-1:2001/EN 61010-1:2001 - Safety requirement for electrical equipment for measurement, control, and laboratory use –Part 1: General requirements
IEC 62304: 2008 - Medical device software-Software life-cycle processes

Roxanne L. Wilson
On behalf of Ronda Elliott
Vice President, Quality and Regulatory Affairs

10/27/2016
Date Issued

T-003
ECO: 448081
Rev. No.: 1

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Year CE Mark attached 13
last 2 digits

Associated product part numbers for **NOVA View® Automated IFA Microscope**

Part Number	Description
AKL1000	**NOVA View® Automated IFA Microscope**
0764275	NOVA View FITC Calibration Slide
NV1006	Olympus 1x81Inverted IFA Microscope with 4x, 10x and 40x Objectives
NV1007	Microscope Stage with Cover
NV1008	Olympus Control Box 1x2 – UCB-2
NV1009	CoolLED Precise Excite with Black Collimator and Light Guide
NV1010	Shuttle PC with PCI Stage Control Board
NV1011	Monitor
NV1012	Collimator, Black (1.0)
NV1013	Camara:Kappa DX4-285FW Digital
NV1014	Fluorescence Mirror Unit
NV1015	Service Tool Kit
NV1018	EU Cable Kit
NV1019	Microscope Stage with Flip Cover
NV1021	Microscope Slide Frame (4 Slide) for Stage
NV1023	NOVA View 1.0 Hood with Fan
NV1050	NOVA View® HEp-2 Software Module
NV1051	NOVA View® ANCA Ethanol/Formalin Software Module *Available outside of U.S. Only
NV1052	NOVA View® Crithidia Software Module *Available outside of U.S. Only
NV2011	Fiber Optic Cable Set, LED Light Guides
NV2015	Microscope 5 Slide Nest for Stage
NV2016	Microscope 5 Slide Carrier Frame with Lid
NV2017	DAPI LAM LED Array Module, 400nm
NV2019	FITC LAM LED Array Module, 400nm
D52030	UPC (Backup Power Supply) *Available in the US Only, not available for export
LINK019	Handheld Barcode Scanner