

## DECLARATION OF CONFORMITY NOVA View® 2.0 Automated Fluorescence Microscope

Unique Device Identifier (UDI) -Primary DI 08426950621614
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**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:** 61864 - Cell morphology analyser IVD, automated

**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

Associated product part numbers for **NOVA View® 2.0 Automated Fluorescence Microscope**

<u>Part Number</u>	<u>Description</u>
<b>NV2000</b>	<b>NOVA View® 2.0 Automated Fluorescence Microscope</b>
0764275	NOVA View FITC Calibration Slide
NV1011	Monitor
NV1015	Service Tool Kit
NV1018	EU Cable Kit
NV1019	Microscope Stage with Flip Cover
NV1021	Microscope Slide Frame (4 Slide) for Stage
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
NV2006	Olympus 1x83 Inverted IFA Microscope with 4x, 10x and 40x Objectives
NV2007	Microscope Stage IX M-MS-PCI-2 With Cables
NV2008	Olympus Control Box 1x3-CBH
NV2009	CoolLED Precise Excite with White Collimator and Light Guide Set
NV2010	Shuttle PC with Win 7 and PCI Stage Control Board
NV2011	Fiber Optic Cable Set, LED Light Guides
NV2012	Collimator, White (2.0)
NV2013	Camera: Zelos 285M Digital with Power Supply
NV2014	Fluorescence Mirror Unit With DAPI/FITC Filter
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
NV2023	NOVA View 2.0 Hood with Fan
D52030	UPC (Backup Power Supply) *Available in the U.S. Only, Not Available for Export
LINK019	Handheld Barcode Scanner
ALDR1000	AUTOloader System for NOVA View