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DECLARATION OF CONFORMITY

QUANTA-Lyser® 3000

Part Number	Material	Unique Device Identifier (UDI) – Primary DI
VS3000	QUANTA-Lyser® 3000 ELISA/IFA	08426950865094
VS3000i	QUANTA-Lyser® 3000 ELISA/IFA + Incubator	08426950865100
VS3002	QUANTA-Lyser® 3000 IFA	08426950865131

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

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

Inova Diagnostics, Inc. hereby declares that the product(s) listed 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: 21 01 43 – Large Automated CC Analyzer
GMDN Code: 56676 – Laboratory multichannel clinical chemistry 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
RoHS 2 Directive 2011/65/EU

Standard(s):
ISO 13485:2016– Medical Devices – Quality management systems. Requirements for regulatory purposes.
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) – Part 1: Terms, definitions, general requirements
ISO 18113-3:2009 – In vitro diagnostic medical devices –Information supplied by the manufacturer (labelling) – Part 3: In vitro diagnostic instruments for professional use.
ISO 15223-1:2016– Medical Devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements
IEC 61010-1:2010 (3rd Ed) – Safety requirement for electrical equipment for measurement, control, and laboratory use – Part 1: General requirements
IEC 61010-2-010:2014 (3rd Ed) Part 2-010: Particular requirements for laboratory equipment for the heating of materials
IEC 61010-2-081:2015 (2nd Ed.) Part 2-081 –Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes

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IEC 61010-2-101:2015 (2nd Ed.) used in conjunction with IEC 61010-1:2010 (3rd Ed)– Safety requirement for electrical equipment for measurement, control, and laboratory use; Part 2:101 - Particular requirements for in vitro diagnostic (IVD) medical equipment.
IEC 61326-1:2012(ed.2) –Electrical equipment for measurement, control and laboratory use – EMC requirements, Part1 – General requirements
IEC 61326-2-6:2012 Electrical equipment for measurement, control and laboratory use – EMC requirements, Part 2-6: Particular requirements – in vitro diagnostic (IVD) medical equipment
CISPR 11 (ed.5); am1 class B - Industrial, scientific and medical equipment - Radio-frequency disturbance characteristics – Limits and methods of measurement
IEC 61000-3-2:2014 (rev.4) – Electromagnetic compatibility (EMC) – Part 3-2: Limits - Limits for harmonic current emissions (equipment input current ≤ 16 A per phase)
IEC 61000-3-3:2013 (ed.3) – Part 3-3: Limits - Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current < 16A per phase and not subject to conditional connection.
IEC 61000-6-2:2005 (ed.2) – Electromagnetic compatibility (EMC) – Generic standard. Immunity standard for industrial environments
IEC 61000-6-3:2006 (ed.2) + am1 - Electromagnetic compatibility (EMC) - Part 6-3: Generic standards - Emission standard for residential, commercial and light-industrial environments.
IEC 62366 – Medical devices – Application of usability engineering to medical devices.
IEC 62304:2006 – Medical Device software – Software life cycle processes
IEC 60825-1:2007 – Safety of laser products – Part 1: Equipment classification and requirements
BS EN 13612:2002 - Performance evaluation of in vitro diagnostic medical devices

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

10-16-2017
Date Issued

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Associated product part numbers for **QUANTA-Lyser® 3000** models:
VS3000, VS3000i, VS3002.

Part Number	Description
23100542	RESA-TRAX 12S INCL. 12 RACKS #100390
23100390	RACK RESA-TRAX 20POS. SAMPLE 12-16MM
23460121	MODULE RESA-TRAX 901 ASSY
23160734	RACK TUBE ASSY INOVA PPS
23160733	RACK TUBE ASSY INOVA FITC IGG (WITHOUT 23210486 & 21210629)
23460227	RACK TUBE ASSY
30119178	PLATE CARRIER 403 ASSY DECK POSITION 1-3
30119245	PLATE CARRIER ASSY DECK POSITION 4-7 *(part not included for models 3001 and 3001i)*
30119270	PLATE CARRIER ASSY DECK POSITION 8-11 *(part not included for models 3001 and 3001i)*
23460132	MODULE WASHER 403 ASSY *(part not included for models 3002)*
23060719	SYSTEM LIQUID 1/4-02
230E0527	READER MICROPLATE 35 WITH FILTER 550NM
230E0003	ADAPTER USB PCAN OPTO DECOUPLED
23485046	CABLE CAN BUS ROBOT DONGLE
23210486	RACK TUBE SET ELISA W. BARCODE
23210629	ADAPTER REMOVER TUBERACK
23210635	ADAPTER SAMPLE TUBE 16-12MM
23160548	STATION TIPWASHER ASSY 4 TIP
30119345	WASTE STATION 401 ASSY
23060721	BOTTLY ASSY 6L SCREW 6*2.5-3.5
23460210	BOTTLY ASSY 2L SCREW 3*4-5
23420146	BAR SUPPORT
230M0836	SCREWDRIVER TORX T20 FUTURO
23132062	CORD POWER US CA BLACK 2M
23132061	CORD POWER UK BLACK 1.5M
23132060	CORD POWER EU BLACK 1.5M
30119406	USB MEMORY STICK 32GB WITH LABEL
230M0840	CLOTH ANTISTATIC SPECIAL
23160581	TOOL ALIGNMENT HANDLER
Document	
399761	Testsheet Instrument (Kopie Seite 1 & 2 mit SN Nr.)
399237	Testsheet READER MICROPLATE 35 (Kopie)
399311	Testsheet MODULE WASHER 403 ASSY (Kopie)
Optional	
30119387	NOTEBOOK MOUNTING ASSY
23420153	PLATE ADAPTER DEEPWELL