LIFEHEALTH
DIAGNOSTICS FOR BETTER HEALTH

EU Declaration of Conformity

According to Annex III of the IVD Directive 98/79/EC

MANUFACTURER: ADDRESS:	EasyDx, Inc. dba LifeHealth also trading as LifeHealth 2656 Patton Road Roseville, Minnesota 55113 - USA
PRODUCT TYPE:	Blood Analysis System
EU Authorized Rep:	MDSS – Medical Device Safety Service Schiffgraben 41 30175 Hannover, Germany Phone +49 511 6262 8630

We hereby declare under our sole responsibility that the products listed in Attachment II are in conformity to the IVD Directive [98/79/EC], RED Directive [2014/53/EU], and RoHS Directive [2011/65/EU] as well as the harmonized standards listed in Attachment I.

Jim Kurkowski
Chief Technical Officer

March 23, 2018
Date

LIFEHEALTH
DIAGNOSTICS FOR BETTER HEALTH

Attachment I: Harmonized Standards

IVD Directive [98/79/EC]	
ISO 13485:2003	Medical devices - Quality management systems - Requirements for regulatory purposes
EN 13612: 2002	Performance evaluation of in vitro diagnostic medical devices
EN 13975: 2003	Sampling procedures used for acceptance testing of in vitro diagnostic medical devices - Statistical aspects
EN ISO 14971:2012	Medical devices - Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01)
EN ISO 15193:2009	In vitro diagnostic medical devices - Measurement of quantities in samples of biological origin - Requirements for content and presentation of reference measurement procedures
EN ISO 15223-1:2012	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
EN ISO 18113-1:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements
EN ISO 18113-2:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use
EN ISO 18113-3:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 3: In vitro diagnostic instruments for professional use
EN ISO 23640:2015	In vitro diagnostic medical devices - Evaluation of stability of in vitro diagnostic reagents
EN 61010-2-101:2002	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment
EN 61326-2-6:2013	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment
EN 62304:2006	Medical device software - Software life-cycle processes
EN 62366:2008	Medical devices - Application of usability engineering to medical devices
Electromagnetic Compatibility (EMC) Directive [2011/65/EU]	
EN 55011:2009 +A1:2010 (CISPR 11:2009/a1:2010)	Industrial, scientific and medical equipment - Radio-frequency disturbance characteristics - Limits and methods of measurement
EN 61326-1:2013 IEC 61326-1:2012	Electrical equipment for the measurement, control and Laboratory use – EMC Requirements, Part 1: General Requirements
IEC 61326-2-6:2013	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment

LIFEHEALTH
DIAGNOSTICS FOR BETTER HEALTH

Attachment I: Harmonized Standards (cont.)

RED Directive [2014/53/EC]	
EN 300 328-1 V2.1.1	Wideband Transmission systems; Data transmission equipment operating in the 2,4 GHz ISM band and using wide band modulation techiques; Harmonised Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU
EN 300 440-1 V1.6.1	Electromagnetic compatibility and Radio spectrum Matters (ERM); Short range devices; Radio equipment to be used in the 1 GHz to 40 GHz frequency range; Part 1: Technical characteristics and test methods
EN 300 440-2 V1.4.1	Electromagnetic compatibility and Radio spectrum Matters (ERM); Short range devices; Radio equipment to be used in the 1 GHz to 40 GHz frequency range; Part 2: Harmonized EN covering essential requirements of article 3.2 of the R&TTE Directive
EN 301 893 V2.1.1	5 GHz RLAN; Harmonized Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU
EN 301 489-1 V1.9.2	Electromagnetic compatibility and Radio spectrum Matters (ERM); Electromagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common Technical Requirements
EN 301 489-17 V2.1.1	Electromagnetic compatibility and Radio spectrum Matters (ERM); Electromagnetic Compatibility (EMC) standard for radio equipment and services; Part 17: Specific conditions for Broadband Data Transmission Systems
EN 301 489-3 V1.5.1	Electromagnetic compatibility and Radio spectrum Matters (ERM); Electromagnetic Compatibility (EMC) standard for radio equipment and services; Part 3: Specific conditions for Short-Range Devices (SRD) operating on frequencies between 9 kHz and 246 GHz
Low Voltage Directive [2014/35/EU]	
IEC 61010-1:2010	Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use - Part 1: General Requirements
IEC 61010-2-010:2014	Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use - Part 2-010: Particular requirements for laboratory equipment for the heating of materials
EN 60950-1:2006 + A11:2009 + A1:2010 + A12:2011	Information Technology Equipment - Safety - Part 1: General Requirements
EN 62311:2008	Assessment of electronic and electrical equipment related to human exposure restrictions for electromagnetic fields (0 Hz - 300 GHz)
RoHS Directive [2011/65/EU]	
EN 50581:2012	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances

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DIAGNOSTICS FOR BETTER HEALTH

Attachment II: Products Covered

IVD	
555700	Irma LH Blood Analysis System

The system consists of the following

Instrument	
443950	Irma Blood Analyzer, Base
428570	Irma Blood Analyzer, Tablet Host
S022-1001X	Power Supply
432150	Temperature Calibration Card
Cartridges/Reagents	
039903	Cartridge, 25pk, Combo
048103	Cartridge, 25pk, Blood Gas (BG)
048400	Cartridge, 25pk, Hematocrit and Electrolyte (H3)
039903-10	Cartridge, 10pk, Combo
048103-10	Cartridge, 10pk, Blood Gas (BG)
048400-10	Cartridge, 10pk, Hematocrit and Electrolyte (H3)
Accessories	
040500	Capillary Device, 50pk