Medimaging Integrated Solution Inc.
ADD: 3F, No. 24-2, Industry E. Rd. IV, Hsinchu Science Park, Hsinchu, Taiwan 30077, R.O.C.
TEL: +886-3-5798860 Fax: +886-3-5798011
URL: http://www.miis.com.tw

Medimaging Integrated Solution Inc.
EC DECLARATION OF CONFORMITY

We,

Medimaging Integrated Solution Inc.
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SRN: TW-MF-000009317

as the manufacturer, declare under our sole responsibility that the following non-sterile products under Rule 13 (Class I) meet the requirements of the Medical Device Regulation (EU) 2017/745 concerning medical devices which apply to them:

Model name	Basic UDI-DI	Common name
MiiS Horus Scope DSC 100	47198727100007L	Control Unit (Class I)
MiiS Horus+ Scope DSC 200		Control Unit (Class I)
MiiS Horus+ Scope DSC 200P		Control Unit (Class I)
MiiS Horus Scope DSC 300		Control Unit (Class I)
MiiS Horus Scope DSC 300P		Control Unit (Class I)
MiiS Horus Scope DEC 100	47198727110007T	Optical Lens of Digital Eye Fundus Camera (Class I)
MiiS Horus Scope EEC 100		Optical Lens of Digital Eye Fundus Camera (Class I)
MiiS Horus+ Scope DEC 200		Optical Lens of Digital Eye Fundus Camera (Class I)
MiiS Horus Scope DOC 100	471987271200082	Optical Lens of Digital Otoscope (Class I)
MiiS Horus Scope DOC 100S		Optical Lens of Digital Otoscope (Class I)
MiiS Horus Scope DOC 300S		Optical Lens of Digital Otoscope (Class I)
MiiS Horus+ Scope EOC 100		Digital Otoscope (Class I)
MiiS Horus Scope EOC 700		Digital Otoscope (Class I)
MiiS Horus Scope DDC 100	471987271300089	Optical Lens of Digital Dermatoscope (Class I)
MiiS Horus Scope DDC 200		Optical Lens of Digital Dermatoscope (Class I)
MiiS Horus Scope DGC 100	47198727140008G	Optical Lens of Digital Oral camera (Class I)
MiiS Horus Scope DTC 100		Optical Lens of Digital Oral camera (Class I)
MiiS Horus Scope DDM 100		Digital Dental Mirror (Class I)
MiiS Horus+ Scope DGC 200	47198727110027X	Optical Lens of Eye Surface Camera (Class I)
MiiS Horus Scope DEA 100		Optical Lens of Digital Eye Anterior Camera (Class I)
MiiS Horus+ Scope DEA 200	47198727110017V	Optical Lens of Eye Anterior Camera (Class I)
MiiS Horus Scope DEA 200P		Optical Lens of Eye Anterior Camera (Class I)

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ILS 100		MiiS Illumination Light Source (Class I)
MPD 100	47198727130078P	Smart Wound Care device (Class I)
SA 1	471987271700095	Image Management Platform (Class I)
SD 1		Image Management Platform (Class I). Accessory of DEC 200 (Class I)
MiiS Horus Scope Adapter	471987271200184	Endoscope Adapter that connect to Control Unit DSC 100 / DSC 200P (Class I)
MiiS Horus Scope Adapter 300		Endoscope Adapter that connect to Control Unit DSC 300P (Class I)
MiiS Horus Scope DVC 100	NA	Control Unit (Veterinary device, doesn't belong to medical device, series model from DSC 100)
Dental Mirror PDM 100	NA	Accessory of MiiS Horus Scope DTC 100 (Class I)
Coupler	NA	Accessory of Endoscope Adapter (Class I)
Charging Station	NA	Accessory of DSC 100 Control Unit (Class I)
		Accessory of DSC 200 Control Unit (Class I)
		Accessory of DSC 200P Control Unit (Class I)
		Accessory of DSC 300 Control Unit (Class I)
		Accessory of DSC 300P Control Unit (Class I)
Slit Lamp Jig	NA	Accessory of Eye Fundus Camera of MiiS Horus Scope (Class I)
CR 100	NA	Accessory of Control Unit of MiiS Horus Scope (Class I)

- DEC 100, EEC 100 and DEC 200 are the digital hand-held Eye Fundus camera used to record digital photographs and video of fundus (including retina, macula and optic disc) of the human eye and surrounding area.
- DOC 100, DOC 100S, DOC 300S, EOC 100 and EOC 700 are the digital hand-held otoscope used to record digital photographs and video of the human ear's canal and tympanic membrane.
- DDC 100 and DDC 200 are the digital hand-held dermatoscope used to record digital photographs and video of the human skin.
- DGC 100 is a digital hand-held camera used to record digital photographs and video of the human body.
- DEA 100, DGC 200 is a digital hand-held eye surface scope used to record digital photographs and video of surface area of the human eye and surrounding area.

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- DEA 200 and DEA 200P are the digital hand-held eye anterior scope used to record digital photographs and video of anterior segment (including cornea, anterior chamber, and lens) of the human eye and surrounding area.
- DEA 100 with ILS 100 is a light module which can provide light to illuminate the anterior segment of human eyes. It can help physician inspect the anterior segment (including cornea, anterior chamber, and lens) of the human eye and surrounding area.
- DTC 100 is a digital hand-held dental scope used to record digital photographs and video of the oral cavity and surrounding area. PDM 100 is the accessory of DTC 100.
- DDM 100 digital dental mirror and accessories are indicated for used to record digital photographs and video of the mouth or tooth and surrounding area.
- DSC 100, DSC 200, DSC 200P, DSC 300, DSC 300P and DVC 100 are the control unit of MiiS Horus Scope.
- MPD 100 is a digital hand-held wound care device used to record digital photographs, determine the boundary of the wound, and manage the wound care information.
- SA 1 is intended for viewing, archiving, transmitting and storage images.
- SD 1 is a computer program for analysis of retinal images shot by DEC 200. It is an accessory of DEC 200.
- Horus Scope Adapter, Horus Scope Adapter 300 and coupler are designed to connect the control unit of MiiS Horus Scope DSC 100 / DSC 200P, DSC 300P separately and the existing endoscope in the market. The assembly system (control unit & Horus Scope Adapter & coupler & existing endoscope in the market) are used to record digital photographs and video of the body.
- CR 100 is a portable chin rest which is used to stabilize the patient's chin and helped the user to catch the image easily. CR 100 could apply to all of MiiS Horus control units, including DSC 100, DSC 200, DSC 200P, DSC 300 and DSC 300P.

Conformity assessment was performed according to Article 52 (7), Annex II and Annex III of the Medical Device Regulation (EU) 2017/745 and 2011/65/EU ("RoHS").

The following standards were applied to establish the products conformity with the essential requirements of the above directive:

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EC Directive(s)/ Regulation(s)

- Medical Device Regulation (EU) 2017/745
- DIRECTIVE 2011/65/EU
- MEDDEV. 2.7.1 Rev.4 Guidelines on Medical Devices - Clinical Evaluation: A Guide for Manufacturers and Notified Bodies

Reference of standard(s) and amendment(s)

- EN 60601-1:2006/A2:2021 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- EN 60601-1-2:2014/2015 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
- EN 62304:2006/AC:2008 Medical Device Software - Software Life Cycle Processes
- EN ISO 13485:2016/A11:2021 Medical devices - Quality management systems - Requirements for regulatory purposes.
- EN ISO 14971:2019/A11:2021 Medical devices - Application of risk management to medical devices
- EN ISO 15223-1:2021 Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements
- UNE-EN 1041:2009+A1:2014 Information supplied by the manufacturer of medical devices
- EN 60601-1-6:2010/A2:2021 Medical electrical equipment –Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
- EN 62366-1:2015/A1:2020 Medical devices – Application of usability engineering to medical devices
- ISO 10940:2009 Ophthalmic instruments - Fundus cameras (Only for DEC 200)
- EN ISO 15004-1:2020 Ophthalmic instruments - Fundamental requirements and test methods - Part 1: General requirements applicable to all ophthalmic instruments
- ISO 15004-2:2007 Ophthalmic instruments - Fundamental requirements and test methods - Part 2: Light hazard protection (Only for DEC 100, EEC 100, DEC 200, DGC 200, DEA 100 with ILS 100, DEA 200 and DEA 200P)
- EN 62471:2008 Photobiological safety of lamps and lamp systems

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- EN ISO 10993-1:2020 & SIST EN ISO 10993-1:2021 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process. (Only for DEC 100, EEC 100, DEC 200, DOC 100, DOC 100S, DOC 300S, EOC 100, EOC 700, DDC 100, DDC 200) (devices which have patient contact part)
- Radio Equipment Directive 2014/53/EU (Only for DSC 300 and DSC 300P)

"MiiS maintains the ISO 13485 certificate from SGS United Kingdom Ltd. since 2011."

Signatory established within the EU who has been empowered to enter into commitments on our behalf:

MedNet EC-REP GmbH

Registered Address:

Borkstrasse 10, 48163 Münster, Germany

Phone: +49 251 32266-0

Fax: +49 251 32266-22

E-mail: contact@mednet-ecrep.com

SRN: DE-AR-000000002

Representative: Matthias Heinz and Ole Stein

10/05/2023

Issue place and date (DD/MM/YYYY)

<Signature>

<Name> Chu-Ming Cheng

<Position> President

<Stamp>