

Medimaging Integrated Solution Inc. (MiiS)
1F, No.7, R&D Rd. II, Hsinchu Science Park,
Hsinchu, Taiwan 30076, R.O.C.

Medimaging Integrated Solution Inc.

EC DECLARATION OF CONFORMITY

According to annex VII of the Council Directive 93/42/EEC, concerning medical devices

We,

Medimaging Integrated Solution Inc.
1F, No.7, R&D Rd. II, Hsinchu Science Park, Hsinchu, Taiwan 30076, R.O.C.

declare under our sole responsibility that the following non-sterile products under Class I, Rule 12 or Class IIa, Rule 10 meet the provisions of the Council Directive 93/42/EEC, concerning medical devices which apply to them:

MiiS Horus Scope

MiiS Horus Scope DEC 100	Optical Lens of Digital Eye-Fundus Camera (Class IIa)
MiiS Horus Scope EEC 100	Optical Lens of Digital Ophthalmoscope (Class IIa)
MiiS Horus Scope DOC 100	Optical Lens of Digital Otoscope (Class I)
MiiS Horus Scope DDC 100	Optical Lens of Digital Dermatoscope (Class I)
MiiS Horus Scope DGC 100	Optical Lens of Digital Speculum (Class I)
MiiS Horus Scope DEA 100	Optical Lens of Digital Anterior Scope (Class I)
MiiS Horus Scope DSC 100	Control Unit (Class I)
MiiS Horus Scope Adapter	Adapter that connect to Control Unit (Class I)
Charger Station	Charger Station of MiiS Horus Scope (Class I)
Slit Lamp Jig	Attachment of DEC100/EEC 100 (Class I)
Coupler	Coupler that connect to Horus Scope Adapter (Class I)

DEC 100 and EEC 100 is a 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 is a digital hand-held otoscope used to record digital photographs and video of the human ear's canal and tympanic membrane.

DDC 100 is a 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.

Horus Scope Adapter is designed to connect the control unit DSC 100 and the existing endoscope in the market. The assembly system (control unit DSC 100 & Horus Scope Adapter & existing endoscope in the market) can used to record digital photographs and video of the body.

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DEA 100 is a digital hand-held anterior scope used to record digital photographs and video of anterior area of the human eye and surrounding area.

Conformity assessment was performed according to Article 11 (5), Annex VII Section 3 of the Council Directive 93/42/EEC.

The following standards were used to prove the products conformity with the essential requirements of the above directive:

EC Directive(s)	Reference of standard(s) and amendment(s)
93/42/EEC	EN 60601-1:2006 Product Electrical safety.
	EN 60601-1-2:2007 EMC and regulatory compliance.
	EN 62304:2006 Software.
	EN ISO 13485:2012/AC: 2012 Medical devices - Quality management systems - Requirements for regulatory purposes.
	ISO 15004-2 Ophthalmic instruments-Fundamental requirements and test methods Part 2: Light hazard protection: 2/15/2007 (Only for DEC 100 and EEC 100)
	EN ISO14971:2009 Application of Risk Management to Medical Devices.
	EN 980:2008 Graphical symbols for use in the labeling of medical devices.
	EN 1041:2008 Information supplied by the manufacturer of medical devices.
	EN 60601-1-6:2010 Medical electrical equipment -Part 1-6: General requirements for basic safety and essential performance -Collateral standard: Usability.
	EN 62366:2008 Medical devices - Application of usability engineering to medical devices

"We have got the ISO 13485: 2003 and ISO 9001: 2008 certificate from SGS United Kingdom Ltd. since 2011"

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

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06/08/2013
 Issue place and date (DD/MM/YY)

<Signature> *Chu-Ming Cheng*

<Name> Chu-Ming Cheng
 <Position> President

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