

# EC Declaration of Conformity to Medical Devices Directive 93/42/EEC

Manufacturer: Address  
Visbion House Telephone +44 (0)870 850 3486  
Visbion Ltd Gogmore Lane  
Chertsey Fax +44 (0)870 850 3487  
KT16 9AP  
UK

## Device Description – IPACS and OPACS

These are Visbion descriptors of their PACS system and consist of the following elements

Image Viewer Image Web Image Capture and Grading

**Visbion Ltd at the address shown above hereby:**

**Declares that:** The above devices conform to the following relevant provisions of the EC Council

Directive	Amendment	Date	OJ Reference	SI Reference
93/42/EEC		14 June 1993	L169 12 7 1993	3017:1997
98/79/EC	M1	27 Oct 1998	L331 1 7 12 1998	618:2002
2000/70/EC	M2	16 Nov 2000	L313 22 13 12 2000	618:2002
2001/104/EC	M3	7 Dec 2001	L6 50 10 01 2002	697:2003
1882/2003/EC	M4	29 Sep 2003	L284 1 13 10 2003	400:2007
2007/47/EC	M5	5 Sep 2007	L247 21 21 09 2007	2936:2008

Annex II elements are in conformity with ISO13485:2003 requirements as verified by Notified Body SGS - reference 0120

The Devices are in conformity with Annex I requirements and are EC Product Class IIA by virtue of Rules 10 and 12

**Confirms that:** No medicinal products/drugs or animal tissues are incorporated in the devices

**Undertakes to:** Develop, implement and maintain a formal Quality Management System to ensure continued adequacy and efficacy.

Develop, implement and maintain a documented post-production experience monitoring programme, along with notification of incidents deemed necessary under the European Medical Device Vigilance system guidelines.

Inform the Competent Authority of any planned or unplanned significant change to the Device, including any significant design changes.

Name: Dr Stefan Claesen Signed:

Title: Chief Executive Officer Date: 7<sup>th</sup> January 2011

**Signed as Agent for, and Designated Representative of, Visbion Ltd**

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		Fax	+44 (0)870 850 3487

## Device Description – IPACS and OPACS

These are Visbion descriptors of their PACS system and consist of the following elements

PIRILIS (also known as Integrated Patient Record “IPR”) Image Importer Report Transcription	Image World Image Book Image Safe Image Cube Image Print	Image Archive Image Archive Micro Image Archive Entry Level Image Archive Mid-Range Image Archive Enterprise
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2007/47/EC	M5	5 Sep 2007	L247 21 21 09 2007	2936:2008

Annex VII elements are in conformity with ISO13485:2003 requirements

The Devices are in conformity with Annex I requirements and are EC Product Class I by virtue of Rule 12

**Confirms that:** No medicinal products/drugs or animal tissues are incorporated in the devices

**Undertakes to:** Develop, implement and maintain a formal Quality Management System to ensure continued adequacy and efficacy.

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Inform the Competent Authority of any planned or unplanned significant change to the Devices, including any significant design changes.

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