

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

**Manufacturer:** Visbion Ltd  
**Address:** Visbion House  
Gogmore Lane  
Chertsey  
KT16 9AP  
UK

Telephone +44 (0)370 850 3486  
Fax +44 (0)370 850 3487

Visbion, Ltd. declares that the medical device described and listed below is in conformity with all relevant essential requirements and provisions of the Medical Devices Directive 93/42/EEC Annex I and Annex II (excluding Section 4) and that the Technical File containing demonstration of conformity is maintained at the above manufacturer address.

**Device: Medical PACS (Pictures Archiving and Communication): Medical Imaging Management software used for image manipulation and diagnostics, which is comprised of the following elements:**

Image Archive      Image Web      Image Viewer      Image Importer      Image Capture

**Configurations of the above elements are additionally marketed and sold under the following trade names:**

Image Archive    Image Archive    Image Archive    Image Archive    Image    Image    Image    IPACS    OPACS  
Micro (Plus)    Entry-Level    Mid-Range    Enterprise    Cube    World    Book

Visbion, Ltd has applied the following standards to the Device: ISO13485, ISO14971, IEC62304, and IEC62366.

Visbion, Ltd confirms that the Device is in conformity with Annex I requirements and is EC Product Class IIa by virtue of Rule 10.

Visbion, Ltd confirms that Annex II elements are in conformity with ISO13485:2003 requirements as verified by Notified Body - SGS United Kingdom Limited - reference 0120, Certificate No: GB08/73961.

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

Name: Dr Stefan Claesen

Signed:



Title: Chief Executive Officer

Date: 24 NOV 2016