

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

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Visbion, Ltd. declares under its sole responsibility that the medical device described and basic UDI-Dis listed below are 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 Medical Devices Regulation 2017-745 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 (IA4.1)    Image Web (IW4.1)    Image Viewer (IV4.1)    Image Capture (4.1)

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

Image Archive Micro (Plus)	Image Archive Entry-Level	Image Archive Mid-Range	Image Archive Enterprise	Image Cube	Image World	Image Book	IPACS	OPACS
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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 risk classification 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 Belgium - reference 1639, Certificate No: GB19/964846.

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

Name: Thomas Falcon

Signed:



Title: Chief Operating Officer

Date: 04 Feb 2022