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

Manufacturer:	**Address:**		
Visbion Ltd	Visbion House Gogmore Lane Chertsey KT16 9AP UK	Telephone Fax	+44 (0)370 850 3486 +44 (0)370 850 3487

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 (IC4.1) Image Display (ID4.1)

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

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: 27 May 2022