

DECLARATION OF CONFORMITY

This document declares that the following designated products:

Manufacturer: **iRay Korea Limited**

1833, 18F, 5, Gasan digital 1-ro, Geumcheon-gu, Seoul, Korea

Product name: Flat Panel Detector

Model name: Mars1717V-VSI

Software: DR Console Software

Related standards:

Safety IEC 61000-4-4, IEC 61000-4-2, IEC 61000-4-3, IEC 61000-4-8, IEC 61000-4-5, IEC 61000-4-6, IEC 61000-4-11

EMC IEC60601-1-2, CISPR 11 (Group 1, Class B), IEC61000-3-2 (Class A), IEC61000-3-3

Directive 93/42/EEC

EN ISO13485:2012/EN

ISO13485:2012/AC:2012

EN ISO14971:2012

IEC 60601-1:2015

The above product herewith complies with the requirements of Korea Good Manufacturing Practices of Medical Devices and relevant harmonized standards applied for the above product, and a declaration of conformity with the medical device directive has been completed and signed by the manufacturer.

Republic of Korea
November 01, 2021



Ji Hong Jung
General Manager
For and on behalf of iRay Korea Limited



iRay Korea Limited
JH. JUNG

JH. JUNG General Manager