EC Declaration of Conformity

EC Certification Number: DRA-1417S-ECDC/Issue Date: 27th March. 2021 –Valid Until 26th March. 2024

Manufacturer: ASTEL Inc.
26-79, Gajeongbuk-ro, Yuseong-gu, Daejeon
34113, Korea

We, the manufacturer, herewith declare that the products

Digital Flat Panel X-ray Detector: DRA-1417SG / DRA-1417SC
Power Supply & System Control Unit: RFA-PCON
Image Acquisition S/W: DMS

GMDNS-Code: [61108]

Has been classified to class IIb according to the rule 10, Annex IX of the Directive 93/42/EEC.
The product concerned has been designed and manufactured under a quality management system according to Annex II (excluding 4) of Directive 93/42/EEC as amended by Directive 2007/47/EC.
The designed product in compliance with the Directive 93/42/EEC has been assessed by the testing laboratory.

following the procedure relating to the EC Declaration of Conformity set out in Annex II of Directive 93/42/EEC.
This Declaration of conformity is valid in connection with the release document for the respective batch of produced devices.
This Declaration of Conformity covers all medical devices as specified in the product list belonging to this declaration and is only valid in connection with a batch specific Certificate of Compliance for all products.

1. The standards relevant for the evaluation of electrical safety requirements are as follows:

EN 1041:2008	Information supplied by the manufacturer with medical devices
EN ISO 13485:2016/AC:2016	Medical devices - Quality management systems - Requirements for regulatory purposes
EN ISO 14971:2012	Medical devices - Application of risk management to medical devices
EN 62366:2008	Medical device - Application of usability engineering to medical device (IEC 62336:2007)
EN 60601-1:2006/A1:2013	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC60601-1:2005)
EN 60601-1-6:2010	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability
EN 60601-1-2:2015	Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests (IEC 60601-1-2:2014)
EN 62220-1:2004	Medical electrical equipment - Characteristics of digital X-ray imaging devices - Part 1: Determination of the detective quantum

	efficiency (IEC 6220-1:2003)
EN 62304:2006/AC:2008	Medical device software - Software life-cycle processes
MEDDEV 2.7-1 rev.4 [June.2016]	Clinical evaluation : Guide for manufactures and notified bodies
MEDDEV2.12-1 rev 8 [Jan.2013]	Guidelines on medical device vigilance system
MEDDEV2.12/2 rev.2 [Jan. 2012]	Post Market Clinical Follow up Studies

2. Test Report No.:
   LVD & EMC : MEK-2020-000301

The above mentioned declaration of conformity is exclusively under the responsibility of

ASTEL Inc.

Daejeon, 2021.03.27 — Dong-geun Kim / COO

Place , date — *Legally binding signature, Function*