EU DECLARATION OF CONFORMITY

■ DECLARER

- Manufacturer : REMEDI Co.,Ltd.
- Company address : 2F, 69-14, Sakju-ro 145beon-gil, Chuncheon-si, Gangwon-do, KOREA
- Contact : Tel) +82-2-6930-5891 Fax) +82-2-6930-5892

Declares that the medical devices described hereafter.
This declaration is issued under the sole responsibility of the manufacturer

Product name	Portable x-ray equipment
Model name	REMEX-KA6
Serial No.	-
GMDN code	37643
Certification No.	0068/QCO-DM/072-2017
Issued certificate date	2021.05.25
Expired date	2024. 05. 27 → 2028.12.31. (It is updated as per extension as per Regulation (EU) 2023/607)

Has been classified as class IIb (Annex IX, Rule10) and is in conformity with the essential requirements and provisions of Council Directive 93/42/EEC.

Is subject to the procedure set out in Annex IV(excluding section 4) of Directive 93/42/EEC as amended by Directive 2007/47/EC under the supervision of Notified Body 0068.

The all models are suitable in General requirements for basic safety and essential performance because the test was performed with representative model REMEX-KA6
Applied standards: Refer to [#Attachment]

■ NOTIFIED BODY

- Notified body name : MTIC INTERCERT S.R.L.
- NB address : Via Moscova, 11 20017 - Rho (MI), Italy
- Contact : Tel) +39 02 9301517 Fax) +39 02 9308176 E-mail) istitutomasini@istitutomasini.it

CE 0068

■ EU REPRESENTATIVE

- EU Representative : JaviTech e.K.
- EU Representative address : Sachsenhausener Straße 16, 65824 Schwalbach am Taunus, Germany
- Contact : Tel: +49 6196 4021549, Email: info@javitech.de

Date: July. 15, 2024 Signature:

REMEDI Co.,ltd.
CEO Cho Bong Ho

[# Attachment]

Applied standard list

No.	Standard	Contents
1	EN ISO 13485:2016/AC:2018	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)
2	EN ISO 14971:2019	Medical devices - Application of risk management to medical devices
3	EN 60601-1:2006/A1:2013	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
4	EN 60601-1-2:2015	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
5	EN 60601-1-3:2008/A11:2016	Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment
6	EN 60601-1-6:2010	Medical electrical equipment - Part 1-6: General requirements for safety - Collateral standard: usability
7	EN 60601-2-28:2010	Medical electrical equipment - Part 2-28: Particular requirements for the safety of X-ray source assemblies and X-ray tube assemblies for medical diagnosis
8	EN 60601-2-54:2009	Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy
9	EN 62304:2006/AC:2008	Medical device - Software life cycle
10	EN 62366:2008	Medical devices - Application of usability engineering to medical devices
11	EN ISO 14155:2011	Clinical investigation of medical devices for human subjects - Part 1: General requirements
12	MEDDEV 2.7.1 rev04	Clinical evaluation: Guide for manufacturers and notified bodies
13	MEDDEV 2.12-1 rev8	GUIDELINES ON A MEDICAL DEVICES VIGILANCE SYSTEM
14	MEDDEV 2.12-2 rev2	POST MARKET CLINICAL FOLLOW-UP STUDIES A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES
15	EN 1041:2008	Information Supplied by the Manufacturer with Medical Devices
16	ISO 7010:2011	Graphical symbols - safety colours and safety signs.
17	EN ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
18	IECEE OD-2044-Ed.2.2	Guidance for the evaluation of risk management in medical electrical equipment