EC DECLARATION OF CONFORMITY

■ DECLARER (Certificate No.: 0068/QCO-DM/072-2017)

- Manufacturer : REMEDI Co., Ltd.
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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-T100, REMEX-K100
Serial No.	-
GMDN code	44606
Certification No.	0068/QCO-DM/072-2017
First issue	2017.09.15
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 (AnnexIX, Rule10) and is in conformity with the essential requirements and provisions of Council Directive 93/42/EEC.

The product does not contain medicinal substance and human blood or derivatives.
And not contain animal originated tissue, phthalates and forbidden substances.

Is subject to the procedure set out in Annex II(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-T100 and REMEX-K100.

Applied standards: Refer to [#Attachment]

This DoC is included in the user's manual of REMEX-T100, REMEX-K100

■ 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

■ 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	IEC 60601-2-65:2012	Medical electrical equipment - Part 2-65: Particular requirements for the basic safety and essential performance of dental intra-oral X-ray equipment
8	EN 62304:2006/AC:2008	Medical device - Software life cycle
9	EN 62366:2008	Medical devices - Application of usability engineering to medical devices
10	EN ISO 14155:2011	Clinical investigation of medical devices for human subjects - Part 1: General requirements
11	MEDDEV 2.7.1 rev04	Clinical evaluation: Guide for manufacturers and notified bodies
12	MEDDEV 2.12-1 rev8	GUIDELINES ON A MEDICAL DEVICES VIGILANCE SYSTEM
13	MEDDEV 2.12-2 rev2	POST MARKET CLINICAL FOLLOW-UP STUDIES A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES
14	EN 1041:2008	Information Supplied by the Manufacturer with Medical Devices
15	ISO 7010:2011	Graphical symbols - safety colours and safety signs.
16	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
17	IECEE OD-2044-Ed.2.2	Guidance for the evaluation of risk management in medical electrical equipment