EC 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	Intra-oral digital X-ray sensor
Brand name	R-SENSOR
Model name	IoDS-2401, IoDS-2402
Serial No.	
GMDN code	44905
Certification No.	0068/QCO-DM/309-2021
Issued certificate date	2021.02.23
Expired date	2024.05.27

Has been classified as class IIa (AnnexIX, Rule16) 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 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 IoDS-2401 and IoDS-2402.
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

■ 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: January 08, 2024 Signature: _____

REMEDI Co., Ltd.
CEO Cho Bong Ho

[# Attachment]

Applied standard list

No.	Standard	Contents
1	ISO 13485:2016	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 60601-1-6:2010	Medical electrical equipment - Part 1-6: General requirements for safety - Collateral standard: usability
6	EN 62304:2006/AC:2008	Medical device - Software life cycle
7	EN 62366:2008	Medical devices - Application of usability engineering to medical devices
8	EN ISO 14155:2011	Clinical investigation of medical devices for human subjects - Part 1: General requirements
9	MEDDEV 2.7.1 rev04	Clinical evaluation: Guide for manufacturers and notified bodies
10	MEDDEV 2.12-1 rev8	GUIDELINES ON A MEDICAL DEVICES VIGILANCE SYSTEM
11	MEDDEV 2.12-2 rev2	POST MARKET CLINICAL FOLLOW-UP STUDIES A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES
12	EN 1041:2008	Information Supplied by the Manufacturer with Medical Devices
13	ISO 7010:2011	Graphical symbols - safety colours and safety signs.
14	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
15	IECEE OD-2044-Ed.2.2	Guidance for the evaluation of risk management in medical electrical equipment