

EU DECLARATION of CONFORMITY (DoC)

This declaration of conformity is issued under the sole responsibility of the manufacturer:

Name: R ZERO Inc.

Address: 2-218, kamo-cho, Yonago-shi, Tottori 683-0823, JAPAN

We declare that the DoC is issued under our sole responsibility and belongs to the following product.

Object of the declaration:

Next Generation Medical

Product Name Simulator mikoto

Gastrointestinal Endoscopy

Model

Model Name R0GT01

Software Name mikoto simulator Software Ver. Ver.02 or later

(Non reconfigurable radio)

Build Version/

Revision Level AA

AC Adapter

Accessories Operator's camera

USB analog video capture

Lubricant



The object of the declaration described above is in conformity with the relevant Union harmonization legislation:

Radio Equipment (RE) Directive (2014/53/EU)

RoHS Directive (2011/65/EU+(EU)2015/863)

The following harmonized standards and technical specifications have been applied:

Health & Safety EN 62368-1:2018 (Article 3.1(a)): IEC 62368-1:2014

EN 62311: 2008

EMC EN IEC 61000-6-3:2021

(Article 3.1(b)): EN IEC 61000-6-1:2019

EN 301 489-1 V2.2.3 EN 301 489-17 V3.3.1

Radio Spectrum EN 300 328 V2.2.2 (Article 3.2): EN 301 893 V2.1.1

RoHS EN IEC 63000:2018

Signed for and on behalf of:

Tottori, JAPAN July 24, 2025

Place of Issue: Date of Issue: Masashi Fujii CEO

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