

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:

Product Name	Next generation Medical Simulator mikoto Colonoscopy Model
Model Name	R0CT01
Software Name	mikoto simulator
Software Ver.	Ver.07 or later (Non reconfigurable radio)
Build Version/ Revision Level	AA
Accessories	AC Adapter Operator's camera 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
(Article 3.1(a)): EN 62368-1:2018
IEC 62368-1:2014
EN 62311: 2008

EMC
(Article 3.1(b)): EN IEC 61000-6-3:2021
EN IEC 61000-6-1:2019
EN 301 489-1 V2.2.3
EN 301 489-17 V3.2.4

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

RoHS EN IEC 63000:2018

Signed for and on behalf of:

Tottori, JAPAN

Place of Issue:

February 22, 2024

Date of Issue:



Masashi Fujii
CEO