EU DECLARATION OF CONFORMITY

MANUFACTURER

Rexxam Co., Ltd. Kagawa Factory
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SRN : JP-MF-000004361

AUTHORIZED EUROPEAN REPRESENTATIVE

Rexxam Co., Ltd. Netherlands Office
Steennovenweg 5, 5708HN Helmond, The Netherlands

SRN : NL-AR-000002643

MEDICAL DEVICE

Model Name	: SLIT LAMP RS-5000
Classification	: Class I (based on the rule 13 of MDR Annex Ⅷ)
Serial number	: effective from 52DX0377 (Main Unit)
	: effective from 52DY0377 (Power Supply Box)
Intended Purpose	: A transparent body such as the cornea or crystalline lens of the eyeball is irradiated with slit light from an oblique direction to perform light cutting, Microscopic abnormalities are raised by the diffused light from the tissue, and magnification observation is performed with a stereoscopic microscope.

THE BASIC UDI-DI 45400080000837

This declaration is only valid for the manufactured products with the document released by us of each product.

The undersigned hereby declares that the medical device as specified above conforms with the General Safety and Performance Requirements listed in Annex I of Regulation (EU) 2017/745.

This declaration of conformity is based on the Regulation (EU) 2017/745 Annex Ⅳ.

The device that is covered by the present declaration is in conformity with this Regulation and, with any other relevant union legislation that provides for the issuing of an EU declaration of conformity.
We declare that we are exclusively responsible for this declaration.

Kagawa Factory, 30.March.2023
Place and date of issue

S. Takashima
Name, signature and
position of manufacture
Development Dept.1 Manager
Shunji Takashima

RE-A06A-B002-D