EU DECLARATION OF CONFORMITY

MANUFACTURER

Rexxam Co., Ltd. Kagawa Factory
958 Ikeuchi, Konan-cho, Takamatsu-shi, Kagawa-ken,
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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

Trade name	: 3in1Smart
Classification	: Class IIa (based on Rules 1, 10, and 11 of MDR Annex VIII)
Serial number	: effective from X2EG0074
Intended Purpose	: This device aims to objectively measure the refractive power of the eye and to measure the corneal curvature radius and the intraocular pressure.
The Basic UDI-DI	: 4540008000102S

NOTIFIED BODY

Name	: BSI Group The Netherlands B.V.
Identification number	: NB 2797
Conformity assessment procedure	: MDR Annex IX Chapter I, III
Identification of the certificate	: MDR 797941

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

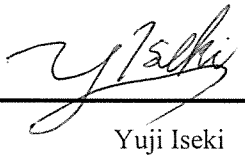
The undersigned hereby declares that the medical device as specified above conforms with the General Safety and Performance Requirements listed in Regulation (EU) 2017/745 Annex I.

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.

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

Kagawa Factory, October 28, 2026

Place and date of issue



Yuji Iseki
General Manager
Research & Development Dept.1