

EC DECLARATION OF CONFORMITY

MANUFACTURER

Rexxam Co., Ltd. Kagawa Factory
958, Ikeuchi, Konan-cho, Takamatsu-city, Kagawa 761-1494 JAPAN

AUTHORIZED EUROPEAN REPRESENTATIVE

Rexxam Czech s.r.o.
Prumyslova 937, 334 01 Prestice, Czech Republic

MEDICAL DEVICE

Model Name : Auto Lensmeter
Model number : Auto Lensmeter DL-1000
Classification : Class I
Serial number : effective from 160011J

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

The undersigned hereby declares that the medical device as specified above conforms with the essential requirements listed in Annex I of EC Directive 93/42/EEC.

This declaration of conformity is based on the EC Directive 93/42/EEC Annex VII, with reference to articles 1 and 3 of directive 93/42/EEC.

The following standards are applicable:

EN 60601-1:2006/A1:2013

Medical electrical equipment
Part 1:General requirements for safety

EN 60601-1-2:2015


Medical electrical equipment
Part 1-2:General requirements for safety
Collateral standard : Erectromagnetic compatibility -
Requirements and tests

Date CE Mark was affixed : February. 12, 2016

We declare that we are exclusively responsible for this declaration.

Kagawa Factory, Feb 12, 2016

Place and date of issue



Masakatsu Iwamoto

Manager of Development Dept.1 at Kagawa Factory