

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 Co., Ltd.
Prumyslova 937, 334 01 Prestice, Czech Republic

MEDICAL DEVICE

Model Name : Auto Lensmeter
Model number : Auto Lensmeter DL-800
Classification : Class I
Serial number : effective from 840011M

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/AC:2010

Medical electrical equipment
Part 1:General requirements for safety

EN 60601-1-2:2007/AC:2010

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

Date CE Mark was affixed : October. 16, 2014

We declare that we are exclusively responsible for this declaration.

Kagawa Factory, Oct.16, 2014

Place and date of issue



Signature, name, and position
of responsible person

Masakatsu Iwamoto

Manager of Development Dept.1 at Kagawa Factory