

RIGHT MFG. CO., LTD.

MANUFACTURER'S DECLARATION OF CONFORMITY

We declare the compliance of the equipment with the requirements of the MEDICAL DEVICE Directive as follows.

KIND OF EQUIPMENT : GS LED Slit Lamp

MODEL NAME : MW50D

CLASSIFICATION : Class I device (The rule 12 of ANNEX IX of the 93/42/EEC)

Declared for the EC directive

Applicable Directives:

93/42/EEC -Medical Devices Directive
ANNEX VII : Refer to Device master file : L0-150270-00

European Representative:

Medical Device Safety Service GmbH
Schiffgraben 41, 30175 Hannover, Germany

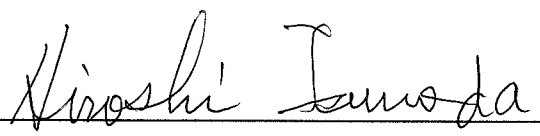
Applicable Standards:

EN 60601-1 : 2006+Amd1:2013 (IEC60601-1:2005+Corr.1+Coor.2 +Amd1:2012)
EN 60601-1-2 : 2014 (IEC60601-1-2 :2014)
EN 62304 : 2006 (IEC62304 :2006)
EN 62366 : 2008 (IEC62366 :2007+Amd1:2014)
EN ISO 10993-1 : 2009 (ISO10993-1 :2009)
EN ISO 14971 : 2012 (ISO14971 :2007)
EN ISO 15004-1 : 2009 (ISO15004-1 :2006)
EN ISO 13485 : 2012 (ISO13485 :2003)

TRADE NAME : SHIGIYA
MANUFACTURER : RIGHT MFG. CO., LTD.
1-47-3, MAENO-CHO, ITABASHI-KU,
TOKYO, 174-8633 JAPAN

CERTIFIED BY :

DATE : 15 June, 2017


HIROSHI TSUNODA / PRESIDENT RIGHT MFG. CO., LTD.