EU DECLARATION OF CONFORMITY

MANUFACTURER: *GRI Medical & Electronic Technology Co., Ltd.*
1805 Honggao Road
314031 Jiaxing, Zhejiang
PEOPLE'S REPUBLIC OF CHINA

EUROPEANREPRESENTATIVE: *Emergo Europe B.V.*
Westervoortsedijk 60,
6827 AT Arnhem,
The Netherlands

PRODUCT*: Light Handle Cover* (refer to see the attached 1)

CLASSIFICATION: Class Ⅰ, Sterile, according to MDD93/42/EEC Annex Ⅸ, Rule 1.

CONFORMITY ASSESSMENT
ROUTE: Annex Ⅴ+Ⅶ, MDD 93/42/EEC(amended by 2007/47/EC)

Medical Device Directive: *COUNCIL DIRECTIVE 93/42/EEC*
(MDD 93/42/EEC) (amended by 2007/47/EC)

We herewith declare in our own responsibility that devices listed on above meet the transportation into national law, the provisions of the above EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer. We are exclusively responsible for the declaration of conformity.

NOTIFIED BODY: *TUV SUD Product Service GmbH,Ridlerstr.65•80339 Munich, Germany*

EC CERTIFICATE*: G2S 056820 0038 Rev.04*

START OF CE-MARKING: 2013-07-01

SIGNATURE: Sidonia Dong 2021/05/20

NAME POSITION: Sidonia Dong VP of RA/QA AP

Attached 1

Part #	Description
25-3011-S1	Flexible light handle cover_Green_Sterile_128EA/CS
25-3011-S2	Flexible light handle cover_Green_Sterile_160EA/CS
25-3011-S3	Flexible light handle cover_ Green_Sterile_240EA/CS
25-3611-S1	Light Handle Cover_Flexible_Green_Sterile_120ea/cs
25-3611-S2	Light Handle Cover_Flexible_Green_Sterile_120ea/cs
25-3611-S3	Light Handle Cover_Flexible_Green_Sterile_150ea/cs
25-3613-S1	Light Handle Cover_Universal_Plastic Base_Blue_sterile_100ea/cs
25-3621-S1	Light Handle Cover_Universal_Foam Base_Sterile_100ea/cs
25-3621-S2	Light Handle Cover_Universal_Foam Base_Sterile_100ea/cs
25-3613-C-S	Light Handle Cover_C_sterile_100ea/cs
26-3612C-S2	Light Handle Cover_A_sterile_2ea/bag_100ea/cs
4000420	Flexible light handle cover_Green_Sterile_100EA/CS
CH128-1FG	Light handle cover_Green_Sterile_128EA / CS
CH160-2FG	Light handle cover_Green_Sterile_160EA / CS
CH240-3FG	Light handle cover_ Green_Sterile_240EA / CS
63049-00	Light Handle Drape_sterile_80ea/cs