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*: Diathermy Pouch* (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: 2015-10-30

SIGNATURE: Sidonia Dong 2021/05/20

NAME POSITION: Sidonia Dong VP of RA/QA AP

Attached 1

Part #	Description
80-14806C	Diathermy Pouch, 30x50cm, 3-Pockets, w/ Adhesive_Sterilized_250ea/cs
80-14804-S	Diathermy Pouch_40x32cm_2-Pockets_w/ adhesive_Sterile_100EA/cs(50Pairs)
80-14807-S	Diathermy Pouch_33x28cm_1-Pocket_w/ Adhesive_Sterile_100ea/cs
80-14805-S	Diathermy Pouch_40x32cm_2-Pockets_w/ adhesive_Sterile_100ea/cs
80-14806-S	Diathermy Pouch_30x50cm_3-Pockets_w/ adhesive_Sterile_100ea/cs
80-14817-S	Diathermy Pouch with 2 compartments (33x28cm)
80-14809-S	Diathermy Instrument Pouch_30X38cm_1 Compartment_Stterile_100ea/cs