

EU DECLARATION OF CONFORMITY

Manufacturer: GRI Medical & Electronic Technology Co., Ltd.

1805 Honggao Road

314031 Jiaxing, Zhejiang

PEOPLE'S REPUBLIC OF CHINA

MF's SRN: CN-MF-000004203

EU Authorized Representative: Emergo Europe B.V.

Westervoortsedijk 60,

6827 AT Arnhem,

The Netherlands

AR's SRN: NL-AR-000000116

Device: Tip Cleaner (refer to see the attached 1)

Basic UDI-DI: 69319181F023KV

Intended purpose: Tip Cleaners are intended to be used in surgical procedures to clean the electrocautery cautery blades of excess tissue with using a physical action.

Classification: Class I sterile, according to MDR 2017/745 Annex VIII, Rule 1

Notified Body Name: TUV SUD

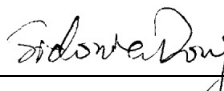
Notified Body Identification Number: 0123

Conformity Assessment Procedure: Annex IX Chapters I and III, MDR 2017/745

CE Certificate: G11 056820 0042 Rev.01

Applicable standards or Common Specifications: N/A

The device covered by the present EU declaration is in conformity with the (EU) MDR 2017/745. All supporting documentations are retained under the premises of the manufacturer. We are exclusively responsible for the declaration of conformity.

Signature/Date:  2024/07/30

Print Name/Position: Sidonia Dong VP RA&QA Asia Pacific

Place: Jiaxing, China

Attached 1

Part #	Description
25-0200-S	Tip cleaner cautery_ Sterile_ 100ea/cs
TC0001	Tip cleaner cautery_ Sterile_ 100ea/cs