

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 non-sterile, according to MDR 2017/745 Annex VIII, Rule 1

Notified Body Name: N/A Notified Body Identification Number: N/A Conformity Assessment Procedure: Article 19, Annex II, Annex III, MDR 2017/745

CE Certificate: N/A

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:	Sidowe Di	m	2023/03/14
Print Name/Position:	Sidonia Dong	У₽́	RA&QA Asia Pacific
Place: Jiaxing, China			



Attached 1

Part #	Description	
25-0200	Pad_Cautery Pencil_No-sterilize_2000ea/cs	
25-0200BB	Pad_Cautery Pencil_No-sterilize_2000ea/cs	
8900365U	Pad_Cautery Pencil_No-sterilize_2000ea/cs	