

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: Medical Forceps and Clamps (refer to see the attached 1)

Basic UDI-DI: 69319181F015KW

Intended purpose: This product family is non-powered hand-held devices that may be used in various surgical procedures for securing drapes, towels, tubing, or holding gauzes and sponges for cleaning and prepping unbroken skin areas. They do not contact with patient directly, and are single use and non-invasive device.

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: 2024/08/07

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

Place: <u>Jiaxing, China</u>



Attached 1

Part #	Description
25-6005SB-S	Scissors_Plastic/Metal Blades_Sharp/Blunt Tip_Disposable_12cm
	(5in)_Sterile_50ea/cs
25-6005SS-S	Scissors_Plastic/Metal Blades_Sharp/Sharp Tip_Disposable_12cm
	(5in)_Sterile_50ea/cs
26-6005BB-S	Scissors_Plastic/Metal Blades_Blunt/Blunt Tip_ Disposable_12cm
	(5in)_Sterile_50ea/cs
25-0575-S	Towel clamp_sterile_200ea/cs
V25-0562-S	9" Sponge Forceps_PP_Green_Sterile_100ea/cs