

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: Suction Tubing (refer to see the attached 1)

Basic UDI-DI: 69319181F063L9

Intended purpose: Suction tubing is utilized to connect a suction tip to a suction source for the removal of fluid waste and small debris from wounds and surgical sites. This product is single use and used sterile.

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: 2024/07/31

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

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



Attached 1

Part #	Description
70-0506C	Suction tubing 6ft with 3/16" standard push-on Fitting, Non sterile_50ea/cs
70-0510C	Suction tubing 10ft with 3/16" standard push-on Fitting, sterile_50ea/cs
70-0512C	Suction tubing 12ft with 3/16" standard push-on Fitting, Non sterile_50ea/cs
70-0520C	Suction tubing 20ft with 3/16"standard push-on Fitting,Non sterile_50ea/cs
70-0606C	Suction tubing 6ft with 1/4" standard push-on Fitting,non-sterile_50ea/cs
70-0610C	Suction tubing 10ft with 1/4" standard push-on Fitting, non-sterile_50ea/cs
70-0612C	Suction tubing 12ft with 1/4" standard push-on Fitting,non- sterile_50ea/cs
70-0620C	Suction tubing 20ft with 1/4" standard push-on Fitting, Non- sterile_50ea/cs
70-0706C	Suction tubing 6ft with 9/32" standard push-on Fitting, Non-sterile_50ea/cs
70-0710C	Suction tubing 10ft with 9/32" standard push-on Fitting, Non-sterile_50ea/cs
70-0712C	Suction tubing 12ft with 9/32" standard push-on Fitting, Non-sterile_50ea/cs
70-0720C	Suction tubing 20ft with 9/32" standard push-on Fitting, Non-sterile_50ea/cs
70-50130-1	Yankauer Suction, Bulb Tip