

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: Sponge Stick (refer to see the attached 1)

Basic UDI-DI: 69319181F011KN

Intended purpose: The purpose of the GRI sponge stick is to provide a means of applying a liquid skin preparation to the patient's unbroken or uncompromised skin using the handle to allow the clinician to apply the prep solution without touching the foam sponge.

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:  2023/03/14

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

Place: Jiaxing, China

Attached 1

Part #	Description
AR-000182NS	Sponge prep stick_Orange sponge and white prep stick_bulk packaged_1000ea/cs
AR-003415NS	Sponge prep stick_blue sponge and white prep stick_bulk packaged_1000ea/cs
8913033	Sponge prep stick_Orange sponge and white prep stick_bulk packaged 1000ea/cs
85021	Sponge stick 8 inch/20cm_Orange_bulk packaged_1000ea/cs
85022	Sponge stick 6"/15cm_Blue_bulk packaged_1000ea/cs
10-519015	Sponge prep stick_blue sponge and white prep stick_Bulk packaged_1000ea/cs
A7401105	Sponge prep stick_blue sponge and white prep stick_bulk packaged_1000ea/cs
25-2008	Sponge prep stick_Blue sponge and white prep stick_bulk packaged_1000ea/cs
25-2009	Sponge prep stick_Orange sponge and white prep stick_bulk packaged 1000ea/cs
25-2011	Sponge Angled Blue and white prep stick_bulk packaged_1000ea/cs
25-2013	Sponge Wire Cleaning_SM Wing_size 3.5"x1.75"x1"_1000ea/cs
25-2014	Sponge stick_Orange sponge white PS stick_Total length 18cm_Non-sterile, 600ea/cs
25-2015	Sponge Stick_Orange_Square_6x4x2.5cm sponge_Non-sterile_800ea/cs
25-2016	Sponge Wire Cleaning_SM Wing_size 3.5"x3.4"x1"_500ea/cs
25-2100	Sponge cube_blue package_Non-sterile_5X4X3.8cm_1000EA/CS
25-2009BB	Sponge prep stick_Orange sponge and white prep stick_bulk packaged 1000ea/cs
25-2012BB	Sponge prep stick_blue sponge and white prep stick_bulk packaged_1000ea/cs
25-2009C	Sponge prep stick_Orange sponge and white prep stick_bulk packaged 1000ea/cs
25-2010	Sponge prep stick_blue sponge and white prep stick_bulk packaged_1000ea/cs
25-2012	Sponge prep stick_blue sponge and white prep stick_bulk packaged_1000ea/cs
25-2020	Sponge Stick_Non-Sterile_800ea/cs
GRI-1008	SPNG_STICK_20CM_HANDLE_FOAM_HEAD_SQUARE_ORANGE_NS_1000EA/CS
GRI-1009	Sponge prep stick_Orange sponge and white prep stick_bulk packaged_1000ea/cs
GRI-2008	Blue_sponge_stick_1000ea/cs
GRI-2009	Sponge prep stick_blue sponge and white prep stick_bulk packaged_1000ea/cs