

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: Waste Collection Device (refer to see the attached 1)

Basic UDI-DI: 69319181F020KP

Intended purpose: This product family is intended to be used for the collection and disposal of bodily fluids and potentially contaminated materials during surgical procedures. These are disposable, single-use products

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

Notified Body Name: TUV SUD

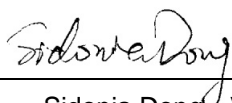
Notified Body Identification Number: 0123

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:  2024/08/14

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

Place: Jiaxing, China

Attached 1

Part #	Description
19-1070-RD-S	Waste Containment Bowl_Red_sterile_20ea/cs
19-1070-YL-S	Waste Containment Bowl_Yellow_sterile_20ea/cs
19-1071-RD-S	Waste Containment Bowl_w/o Solidifier_Red_sterile_20ea/cs Waste Containment Bowl_w/o Solidifier_Red_sterile_20ea/cs
19-1071-YL-S	Waste Containment Bowl_w/o Solidifier_Yellow_sterile_20ea/cs
19-0500-BL-S	WasteStop Waste Containment Basin_Blue_sterile_20ea/cs