

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

Notified Body Name: N/A

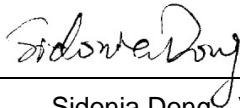
Notified Body Identification Number: N/A

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:  2024/07/30

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

Place: Jiaxing, China

Attached 1

Part #	Description
50-DCCL02	Drawcord Bag_Clear_38inx38inx0.0018in_100ea/cs
50-DCRD03	Drawcord Bag_Red printed_38inx38inx0.002in_100es/cs
0020DCR	Drawcord Bag_Red printed_Non-sterile_38inx38inx0.002in_100es/cs
0021DCB	Drawcord Bag_38inx38inx0.0018in_Blue_Non-sterile_Bulk_100ea/cs
0022DCC	Drawcord Bag_Clear_38inx38inx0.0018in_100ea/cs
DSBL3838	Drawcord Bag_38inx38inx0.0018in_Blue_bulk_100ea/cs
DSBR3838	Drawcord bag_38inx38inx0.0018in_Brown_bulk_N/S_100ea/cs
DSCL3838	Drawcord Bag_Clear_38inx38inx0.0018in_100ea/cs
DSCL4040	Drawcord Bag_Clear_40inx40inx0.0018in_100ea/cs
DSRD3838	Drawcord Bag_Red printed_38inx38inx0.002in_100ea/cs
DSRD4040	Drawcord Bag_Red printed_40inx40inx0.003in_100ea/cs
DSYL3838	Drawcord Bag_38inx38inx0.0018in_Yellow_bulk_100ea/cs
DTBL4040	Draw_Tape_Bag_40in x40in_Blue_bulk_non-sterile_100ea/cs
DTCL4040	Draw_Tape_Bag_40in x40in_Clear_bulk_non-sterile_100ea/cs
DTRD4040	Draw_Tape_Bag_40in x40in_Red_bulk_non-sterile_100ea/cs
DTSOIL	Soiled_Linen_Bag,Draw_Tape 80cmx102cm_printed_bulk_non-sterile_200ea/cs
KBRD22431	Kick Bucket Bag_Red printed_24inx31inx0.0013in_350ea/cs
KBRD2324	Kick Bucket Bag_23in x 24in x 0.0013" _Red with black printing_N/S_500ea/cs
KBRD2431	Kick Bucket Bag_Red printed_24inx31inx0.0013in_350ea/cs
LNCL2530	Kick Bucket Liner_25x30in_Clear_250ea/cs
LNCL3338	Clear Trash Liner Bag_N/S_33inx38inx0.001in_clear_250ea/cs
i50-CART01	Cart Cover_38inx26inx48inx0.0015in_Clear_N/S_100ea/cs
i50-CTB01	Bag_Clear_14"x18"x0.001" _1000ea/cs
i50-CTB02	Bag_clear_14inx24inx0.001in_1000ea/cs
i50-CTB03	Bag_Clear_Infolding_16inx9inx30inx0.001in_Clear_N/S_250ea/cs
i50-CTB05	Bag_Clear_Infolding_38inx60inx0.0015in_Clear_N/S_150ea/cs
i50-CTB06	Clear Trash Liner Bag_N/S_33inx38inx0.001in_clear_250ea/cs
i50-CTB07	Bag_Red printed_21inx29inx46in_100ea/cs
i50-CTB09	Bag_Brown_38inx38inx0.0018in_100ea/cs
i50-CTB11	Bag_Brown_38inx58inx0.0018in_100ea/cs
i50-DCBL01	Drawcord Bag_Blue_29inx38inx0.0015in_150ea/cs
i50-DCBL02	Drawcord Bag_Blue_33inx38inx0.0018in_100ea/cs
i50-DCBL03	Drawcord Bag_38inx38inx0.0018in_Blue_bulk_100ea/cs
i50-DCBRN01	Drawcord bag_33inx38inx0.0018in_Brown_bulk_N/S_100ea/cs
i50-DCBRN02	Drawcord Bag_Brown_Bulk_N/S_120ea/cs
i50-DCBW01	Drawcord Bag_White_38inx38inx0.0018in_100ea/cs
i50-DCCL02	Drawcord Bag_Clear_38inx38inx0.0018in_100ea/cs
i50-DCCL03	Drawcord Bag_Clear_48inx42inx0.002in_100ea/cs
i50-DCCL04	Drawcord Bag_Clear_40inx40inx0.0018in_100ea/cs
i50-DCCL05	Drawcord Bag_Clear_54"x42"x0.008" _50ea/cs

i50-DCRD01	Drawcord Bag_Red printed_29inx38inx0.0015in_150ea/cs
i50-DCRD02	Drawcord Bag_Red printed_33inx38inx0.002in_150ea/cs
i50-DCRD03	Drawcord Bag_Red printed_38inx38inx0.002in_100es/cs
i50-DCRD04	Drawcord Bag_Red printed_40inx40inx0.003in_100ea/cs
i50-DCRD05	Drawcord Bag_Red printed_40inx44inx0.003in_100ea/cs
i50-KBBB01	Kick Bucket Bag_Black_40inx46inx0.0014in_100ea/cs
i50-KBBR01	Kick Bucket Bag_24inx23inx0.0013in_Red with black printing_N/S_250ea/cs
i50-KBBR02	Kick Bucket Bag_Red printed_24inx31inx0.0013in_350ea/cs
19-1070B-RD	Waste Containment Bowl_Red_Bulk_non-sterile_200ea/cs
19-1070B-YL	Waste Containment Bowl_Yellow_Bulk_non-sterile_200ea/cs
19-1070-RD	Waste Containment Bowl_Red_assembled_non-sterile_20ea/cs
19-1070-YL	Waste Containment Bowl_Yellow_assembled_non-sterile_20ea/cs
19-1071B-RD	Waste Containment Bowl_w/o Solidifier_Red_Bulk_non-sterile_200ea/cs
19-1071B-YL	Waste Containment Bowl_w/o Solidifier_Yellow_Bulk_non-sterile_200ea/cs
19-1071-RD	Waste Containment Bowl_w/o Solidifier_Red_Assembled_non-sterile_20ea/cs
19-1071-YL	Waste Containment Bowl_w/o Solidifier_Yellow_Assembled_non-sterile_20ea/cs
28319BID	Drawstring Bag_Plastic_12 x 25 cm_100EA/CS
28404BID	Drawstring Bag_Plastic_18 x 25 cm_100EA/CS
46-SB1206	Suture Bag_white_with printing_6in x 12.5in_1.8mil_Non-Sterile_1000ea/cs
46-SB1812-P	Bag, Suture Bedside, Poly, W/Tape, 12" x 18"
10-519013	Sponge counter bag NS_250ea/cs
25-2990	Sponge counter bag_96cm*25.5cm_Non-sterile_250ea/cs
25-2991	Sponge counter bag_96cm*25.5cm_Non-sterile_With printing_250ea/cs
25-2992	Sponge counter bag_With Adhesive Closure_96cm*25.5cm_Non-sterile_250ea/cs
25-2993	Sponge counter bag_With Adhesive Closure_Blue Print_96cm*25.5cm_Non-sterile_250ea/cs
AR-25500	Sponge counter bag_37*10 1/8"_250ea/cs
AR-25500NS	Sponge counter bag_96cm*25.5cm_Non-sterile_250ea/cs
25-3018	Disposal bag_295mm*165mm*70mm_500ea/cs
50-DCCL04	Drawcord Bag, Clear_Clear_40" x 40"
50-DCCL05	Drawcord Bag, Clear_Clear_54" x 42"
50-DCRD04	Drawcord Bag, Red_Red printed_40" x 40"
50-DCBL03	Drawcord Bag, Blue_Blue_38" x 38" 1.8mil
50-DCBL04	Drawcord Bag, Blue 40" x 40" x 2.5mil
50-DCGRN03	Drawcord Bag,green, 40" x 40" x 2.5mil
50-DTCL01	Draw_Tape_Bag_40in x40in_Clear_bulk_non-sterile_100ea/cs
50-DTRD02	Drawtape Bag, Red, Biohazard, 40in x 40in, 2mil
50-DTBL01	Bag: Drawtape 40in x 40in LG Blu
50-DTBK01	Drawtape Bag, Black, 40in x 40in, 2mil
50-KBBR01	Kick Bucket Bag_Red printed_23" x 24"
50-CTB06	Clear Trash Liner Bag_Clear_33" x 38"
50-DCBRN01	Drawcord Bag, Brown_Brown_38" x 38"

68481-80	Drawcord Bag_Clear_38inx38in_1.8mil_N/S_100ea/cs
68482-80	Drawcord Bag_Clear_40inx40in_1.8mil_N/S_100ea/cs
68483-80	Drawcord Bag_Clear_54inx42in_1.8mil_N/S_50ea/cs
68484-80	Drawcord Bag_Red_Biohazard_38inx38in_2mil_N/S_100ea/cs
68485-80	Drawcord Bag_Red_Biohazard_40inx40in_3mil_100ea/cs
68486-80	Drawcord Bag_Blue_38inx38in_1.8mil_100ea/cs
68487-80	Drawcord Bag_Blue_40inx40in_2.5mil_100ea/cs
68488-80	Drawcord Bag_Green_40inx40in_2.5mil_100ea/cs
68489-80	Drawtape Bag_Clear_40inx40in_1.8mil_100ea/cs
68490-80	Drawtape Bag_Red_Biohazard_40inx40in_1.8mil_100ea/cs
68491-80	Drawtape Bag_Blue_40inx40in_1.8mil_100ea/cs
68492-80	Drawtape Bag_Black_40inx40in_2mil_100ea/cs
68493-80	Kick Bucket Bag_Red_23inx24in_1.3mil_250ea/cs
68494-80	Trash Liner_Clear_33inx38in_1mil_250ea/cs
68495-80	Drawcord Bag_Brown_38inx38in_1.8mil_100ea/cs
AR-77301371NS	Waste Collection Device_1000CC_cover+basin+SAP_Non-sterile_100EA/CS
AR-773031371NS	Waste Collection Device 1000cc_Non-sterilize_100ea/cs