

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: Room Turnover Kit (refer to see the attached 1)

Basic UDI-DI: 69319181F042KZ

Intended purpose: This product family provides products which will be used in the operating room, patient room, or long-term care facilities. These kits and components are designed to protect the patient, staff, and equipment from contamination, aid in the collection of trash and linens, assist in the transfer of the patient to the operating room table and aid in the turnover of the operating room for the next procedure. These are disposable, single-use products.

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

Notified Body Name: NA

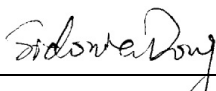
Notified Body Identification Number: NA

Conformity Assessment Procedure: Article 19, Annex II, Annex III, MDR 2017/745

CE Certificate: NA

Applicable standards or Common Specifications: NA

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:  2024-02-27

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

Place: Jiaxing, China

Attached 1

Part #	Description
80-86102	Lift_Sheet_220cmx260cm_Soft_White_Bulk_N/S_25ea/cs
85025	Lift Sheet_160cm x 240cm_Euroguard_White_N/S_48ea/cs
55-6050G	Neonatal Mattress Cover_with elastic_non sterile_bulk_200ea/cs_MD is the width
55-6060FP	Fisher & Paykel warming bed Mattress Cover_61cmx61cmx3.5cm_with elastic_N/S_bulk_200ea/cs
55-7060FP	Fisher & Paykel warming bed Mattress Cover_71cmx61cmx3.5cm_with elastic_N/S_bulk_200ea/cs
55-7640D	Draeger Incubator Mattress Cover__with elastic_N/S_bulk_200ea/cs_MD is the width
55-6550D	Draeger Incubator Mattress Cover__with elastic_N/S_bulk_200ea/cs_MD is the width
55-7335A	ATOM Incubator Mattress Cover__with elastic_N/S_bulk_200ea/cs_MD is the width
55-6537A	ATOM Incubator Mattress Cover__with elastic_N/S_bulk_200ea/cs_MD is the width
55-6749A	ATOM Incubator Mattress Cover__with elastic_N/S_bulk_200ea/cs_MD is the width
55-6544K	Kanmed Babybed BBI Mattress Cover_with elastic_N/S_bulk_200ea/cs_MD is the width
49-RTK04	Basic Core RTK IV_RTK04-01_Non sterile_16ea/cs
49-RPSMRK-01	Pulizia Sala Merano Room Turnaround Kit_Non Sterile_8ea/cs
49-AMBRK01	Ambulance Kit_Stretcher cover_headrest cover_warming blanket_Non Sterile_12ea/cs
49-SORTK-01	CORE Kit Copritavolo Operatorio_Non sterile_24ea/cs
49-SORTK01	CORE Kit Copritavolo Operatorio_Non sterile_24ea/cs
49-RTKSO-9	Absorbent Table Cover_Lift Sheet_Non-sterile_40ea/cs
49-SORTK-03	CORE Kit Copritavolo Operatorio_Absorbent table cover_Lift Sheet_Utility drape_Non sterile_24ea/cs
49-MDRK-01	Absorbent table sheet with elastic borders_lift sheet_arm board covers_head rest cover_Non Sterile_24ea/cs
49-RTK03	Abs Top Sheet_Armboard cover_Head Rest Cover_Non sterile_36ea/cs
49-RTKSO-10	CORE Kit Copritavolo Operatorio_Absorbent table cover_Lift Sheet_Armboard cover_Non sterile_32ea/cs
49-RTKSO-8	Absorbent Table Cover_Lift Sheet_Armboard covers_Non sterile_32ea/cs
49-DISSRTK-01	DISS Room Turnaround Kit_Non Sterile_14 ea/cs
49-RTKMD01	Room Turnaround Kit_Impervious_Lift Sheet_Armboard Cover_Head Rest Cover_Non-sterile_EA/CS
T49-RTK05	Abs Top Sheet_Lift Sheet_Non sterile_40ea/cs
50-LFT004	Lift_Sheet_34inx66in_70gsm_Soft_White_Bulk_N/S_100ea/cs
50-LFT001-1	Lift_Sheet_34inx66in_Soft_White
50-LFT001	Lift_Sheet_34inx66in_Soft_White_Bulk_N/S_100ea/cs
T50-LFT001	Lift_Sheet_34inx66in_Soft_White_Bulk_N/S_100ea/cs
50-LFTSO4061	Lift Sheet_40inx61in_White_50ea/cs
50-LFT002	Lift Sheet_40inx92in_XL_White_50ea/cs
T50-LFT002	Lift Sheet_40inx92in_XL_White_50ea/cs

80-14302	Lift Sheet_40inx80in_50ea/cs
80-14303	Lift Sheet_40inx92in_X-Long_White_50ea/cs
50-LFT003-1	Disposable linens_Lift/Draw Sheet_L_White_40inx80in
50-LFT003	Lift Sheet_Large_40inx80in_50ea/cs
T50-LFT003	Lift Sheet_Large_40inx80in_50ea/cs
50-LFT002-1	Disposable linens_Lift/Draw Sheet_XL_White_40inx92in
50-AMBC01-3	Armboard_Cover_w/_1ea Strap
81-ABC001	Armboard Cover_W/12.5inX29.25in/1.5in Width Strap_150ea/cs
50-AMBC01-1	Armboard_Cover_w/_1ea Strap
50-AMBC01-2	Armboard_Cover_w/_2ea Strap
50-AMBC02-1	Armboard_Cover_w/_2ea Strap
50-AMBC02	Armboard_Cover_w/_2ea Strap_150ea/cs
50-150202	Arm Cradle_12.5 x 16.5 x 9in(32 x 42 x 23cm)_6EA/CS
0184LTA	Lift_Sheet_34inx66in_70gsm_Soft_White_Bulk_N/S_100ea/cs
0184XLTA	Lift_Sheet_32.5in X 92in_70gsm_Soft_White_Bulk_N/S_100ea/cs
49-CSRTK-01	Abs Top Sheet_Lift Sheet_Non sterile_40ea/cs
49-KIT001	Abs Top Sheet_KIT001_Armboard cover_Lift Sheet_Non sterile_40ea/cs
49-KIT002	Abs Top Sheet_KIT002_Lift Sheet_Non sterile_40ea/cs
49-KIT002-HB	Abs Top Sheet_KIT002_Lift Sheet_Non sterile_Handi-Bin_224ea/cs
49-KIT003	Abs Top Sheet_KIT003_Armboard cover_Lift Sheet_Head Rest Cover_Non sterile_40ea/cs
49-RPSMRK-02	Pulizia Sala Merano Room Turnaround Kit_Non Sterile_8ea/cs
49-RTK00	Absorbent Top Sheet Lift Sheet and Armboard covers_Non sterile_36ea/cs
49-RTK01	Absorbent Table Cover and Lift Sheet_Non sterile_40ea/cs
49-RTK02	Abs Top Sheet_Armboard cover_Lift Sheet_Head Rest Cover_Non sterile_36ea/cs
49-SORTK02	Abs Top Sheet_Lift Sheet_Non sterile_36ea/cs
50-AMBC005	Armboard cover (14.5"X30") with two straps_one pair/bag_50bags/cs
50-AMBC01	Armboard_Cover_w/_1ea Strap_150ea/cs
50-AMBC03	Armboard_Cover_w/_1ea Strap_with a slit_150ea/cs
50-HRC001	Head rest Cover_Blue_14inx15in_BULK_N/A_100ea/cs
50-HRC1415	Head rest Cover_Blue_14" x 15" _BULK_N/A_100ea/cs
50-IPC001	Impervious Pillow Cover_Blue_20"X27" _Bulk_N/S_50ea/cs
50-PC1927	Impervious Pillow Cover_Blue_20"X27" _Bulk_N/S_50ea/cs
50-TBLD06C	Table Drape_Impervious_040108001-WG_Non- Sterile_200ea/cs
50-TBLD07C	Table Drape_Impervious_040108006-WG_Non- Sterile_120ea/cs
50-TBLD08C	Table Drape_Impervious_040108009-WG_Non- Sterile_100ea/cs
50-TOWL03	Hand Towel_White_85x57cm (33.5x22.4in)_N/S_50ea/cs
6200-130	Absorbent table sheet with elastic borders_lift sheet_Non Sterile_24ea/cs
6200-131	Absorbent table sheet with elastic borders_lift sheet_arm board covers_Non Sterile_20ea/cs
6200-132	Absorbent table sheet with elastic borders_lift sheet_arm board covers_head rest

	cover_Non Sterile_20ea/cs
80-14301	Lift sheet_40inx60in_white PET nonwoven_non-sterile_50ea/cs
86-01643	Tissue Retrieval Pouch Assembly_5EA/CS_N/S
ABC1330W2S	Armboard_Cover_w/_2ea Strap_150ea/cs
SHTBD4090	Bed Sheet_40in x 90in_50ea/cs
SHTDW5472	Sheet, draw,54x72in, global_60ea/cs
SHTLFT3466	Lift_Sheet_34inx66in_Soft_White_Bulk_N/S_100ea/cs
SHTLFT4080	Lift Sheet_Large_40inx80in_50ea/cs
SHTLFT4092	Lift Sheet_40inx92in_XL_White_50ea/cs
SHTST8537	Fitted Absorbent Sheet_85in x 37in_100ea/cs
SLIDERPT	Patient Transfer Sheet_60ea/cs
i49-ESCRTK-01	Elite Surgery Center RTK_ESCRTK-01_Non sterile_20ea/cs
i49-FMHRTK-01	Falmouth Hospital Core RTK_FMHRTK-01_Non sterile_14ea/cs
i49-HSCRTK-01	Harborside Surgery Center_HSCRTK-01_Non sterile_14ea/cs
i49-LHRTK-01	Cape Cod Core RTK_LHRTK-01_Non sterile_12ea/cs
i49-LHRTK-02	Lowell Hospital RTK_LHRTK-02_Non sterile_12ea/cs
i49-LSCRTK-01	LEGACY ROOM TURNOVER KIT LSCRTK-01_Non sterile_16ea/cs
i49-MRCLRTK-02	Meadows Regional_MRCLRTK-02_Non sterile_40ea/cs
i49-MRORRTK-01	Meadows Regional_MRORRTK-01_Non sterile_32ea/cs
i49-PASCRTK-01	Park Avenue Surgery Center RTK_PASCRTK-01_Non sterile_12ea/cs
i49-RPS003-01	Regional Plastic Surgery RTK_RPS003-01_Non sterile_12ea/cs
i49-RTK00	Room Turnaround Kit, Non Sterile
i49-RTK01	Room Turnaround Kit I, Non Sterile
i49-RTK02	Room Turnaround Kit II, Non Sterile
i49-RTK04	Room Turnaround Kit IV, Non Sterile
i49-RTK04-01	Basic Core RTK IV_RTK04-01_Non sterile_16ea/cs
i49-SMCORRTK-01	Star Medical Room Turnaround Kit_SMCORRTK-01_Non sterile_15ea/cs
i49-SSHRTK01	SouthShore OR Clean Up Kit_SSHRTK01_Non sterile_16ea/cs
i50-AMBC01	Armboard_Cover_w/_1ea Strap_150ea/cs
i50-ATC4030	Absorbent Top Sheet_Blue_40"x30"_non-sterile_packaged_25ea/cs
i50-HRC001	Head rest Cover_Blue_14" x 15"_BULK_N/A_100ea/cs
i50-IPC001	Impervious Pillow Cover_Blue_20"X27"_Bulk_N/S_50ea/cs
i50-LFT001	Lift_Sheet_34inx66in_Soft_White_Bulk_N/S_100ea/cs
i50-LFT002	Lift Sheet_40inx92in_XL_White_50ea/cs
i50-LFT003	Lift Sheet_Large_40inx80in_50ea/cs
80-14107	Armboard covers_35.5x80cm_Non-sterile_280ea/cs
9000-NWLIJ1	Abs Top Sheet_Armboard cover_Lift Sheet_Headrest cover_Non sterile_16ea/cs
9000-TAA2	Combo Pack_Abs Top Sheet_Armboard cover_Lift Sheet_Non sterile_20ea/cs
CM208300	BioMattress Cover_GE Giraffe_N/S_160ea/cs_MD is the width
49-CRDRTK01	Room Turnaround Kit I_Non Sterile_24 ea/cs
49-CRDRTK02	Room Turnaround Kit II_Non Sterile_16 ea/cs

49-CRDRTK03	Room Turnaround Kit III _Non Sterile_16 ea/cs
49-CRDRTK04	Room Turnaround Kit IV _Non Sterile_20 ea/cs
50-TOWL04	Disposable Towel,PET_70gsm White_12" x 12"
49-OMRTK01	Complete Pack with Microfiber Mop
49-OMRTK02	Complete Pack with Rayon Mop
50-LFT007	Lift_Sheet_150cmx100cm_Soft_White_Bulk_N/S_100ea/cs
49-CSRTK-02	Abs Top Sheet_Lift Sheet_Non sterile_40ea/cs
68475-80	Lift Sheet_40inx60in_Soft_White_Bulk_Non-Sterile_100ea/cs
68476-80	Head rest Cover_14inx15in_Blue_BULK_Non-Sterile_100ea/cs
68477-80	Pillow Case_20"X27"_Blue_Bulk_Non-Sterile_50ea/cs
68478-80	Armboard Cover_13inX30in_1ea Strap_N/S_150ea/cs
68479-80	Armboard Cover_13inX30in_with Strap-Through(1ea)_N/S_150ea/cs
68480-80	Wash Cloth_12inX12in_N/S_500ea/cs
68504-80	ATC_LIFT SHEET_ARM BOARD COVER_HEAD REST COVER WITH MICROFIBER MOP_ Wash Cloth_Bags_Non sterile_12ea/cs
68503-80	ATC_LIFT SHEET_ARM BOARD COVER_HEAD REST COVER WITH MICROFIBER MOP_ Wash Cloth_Bags_Non sterile_12ea/cs
68502-80	ATC_LIFT SHEET_ARM BOARD COVER_HEAD REST COVER_Bags_Non sterile_36ea/cs
68501-80	ATC_LIFT SHEET_ARM BOARD COVER_Bags_Non sterile_36ea/cs
68500-80	ATC_LIFT SHEET_Bags_Non sterile_40ea/cs
50-TQTC01	Tourniquet Cover_opening 5x5 cm_dimensions 44x44cm_ Non-sterile_S_200ea/cs
50-TQTC02	Tourniquet Cover_opening 7x10cm_dimensions 44x44cm_Non-sterile_M_200ea/cs
50-TQTC03	Tourniquet Cover_opening 12x16cm_dimensions 58x58cm_Non-sterile_L_200ea/cs