

EU DECLARATION OF CONFORMITY

MANUFACTURER: *GRI Medical & Electronic Technology Co., Ltd.*
1805 Honggao Road
314031 Jiaxing, Zhejiang
PEOPLE'S REPUBLIC OF CHINA

EUROPEAN REPRESENTATIVE: *Emergo Europe B.V.*
Westervoortsedijk 60,
6827 AT Arnhem,
The Netherlands

PRODUCT: *Equipment Covers* (refer to see the attached 1)

CLASSIFICATION: Class I, Sterile, according to MDD93/42/EEC Annex IX, Rule 1.

CONFORMITY ASSESSMENT

ROUTE: *Annex V+VII, MDD 93/42/EEC(amended by 2007/47/EC)*

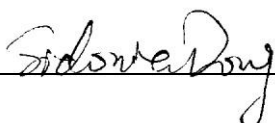
Medical Device Directive: *COUNCIL DIRECTIVE 93/42/EEC*
(MDD 93/42/EEC) (amended by 2007/47/EC)

We herewith declare in our own responsibility that devices listed on above meet the transportation into national law, the provisions of the above EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer. We are exclusively responsible for the declaration of conformity.

NOTIFIED BODY: *TUV SUD Product Service GmbH, Ridlerstr.65•80339 Munich, Germany*

EC CERTIFICATE: *G2S 056820 0038 Rev.04*

START OF CE-MARKING: *2017-09-07*

SIGNATURE:  2021/05/20

NAME POSITION: Sidonia Dong VP of RA/QA AP

Attached 1

Part #	Description
i46-CARM2-S	C-Arm/Mobile_X-Ray_Drape_with_sterile_package_20ea/cs
40-0009-S	Band Bag_Dome Style_sewn elastic_9in circular_bulk_Sterile_25ea/cs
40-0014-S	Band Bag_Dome Style_sewn elastic_14in circular_Sterile_25ea/cs
40-0018-S	Band Bag_Dome Style_sewn elastic_18in circular_Sterile_25ea/cs
40-0020-S	Band Bag_Dome Style_sewn elastic_20in circular_Sterile_50ea/cs
40-0022-S	Band Bag_Dome Style_sewn elastic_22in circular_Sterile_25ea/cs
40-0026-S	Band Bag_Dome Style_sewn elastic_26in circular_Sterile_25ea/cs
40-0027-S	Band Bag_Dome Style_sewn elastic_27in circular_Sterile_25ea/cs
40-0030-S	Band Bag_Dome Style_sewn elastic_30in circular_Sterile_25ea/cs
40-0040-S	Band Bag_Dome Style_sewn elastic_40 in circular_Sterile_25ea/cs
40-0050-S	Band Bag_Dome Style_sewn elastic_50 in circular_Sterile_25ea/cs
40-0060-S	Band Bag_Dome Style_sewn elastic_60 in circular_Sterile_25ea/cs
40-1212-S	Band Bag with Tape and Rubberbands_12inx12in_bulk_Sterile_25ea/cs
40-4436-S	Band Bag with Tape_Sewn Elastic_44inx36in_Sterile_25ea/cs
46-CARM1-S	Universal X-Ray Equipment Drape_41" x 65" _Sterile_50ea/cs
46-CARM2-S	C-Arm/Mobile X-Ray_Drape_42" x 72" _Sterile_50ea/cs
46-CARM3-S	C-Arm/Mobile X-Ray_Drape_42"x 74" _Sterile_50EA/CS
46-CARM4-S	C-Arm Drape Extra Long_41" x 90" _Sterile_50EA/CS
46-CARM5-S	C-Arm cover for fluoroscan standard model_54"x 78" _Sterile_25EA/CS
46-CARM6-S	Universal X-Ray Equipment Drape_41" x 125" _Sterile_50EA/CS
46-CARM7-S	X-Ray Drape_59x104in_Sterile_50EA/CS
46-CARM8-S	C-Arm/Mobile X-Ray Drape_46"x120" _Sterile_50EA/CS
46-CARM10-S	Cover C-Arm_OEC_9800 Clip-System_Sterilize_25EA/CS
46-CARM11-S	Fluoroscope Drape_36" x 44" _Sterile_50ea/cs
46-CARM12-S	X-ray Image Intensifier Drape_41" x 64" _Sterile_package_50ea/cs
46-CARM13-S	C-Arm Pack 9" for OEC/GE 9800_Sterile_50ea/cs
46-CARM14-S	C-Arm Pack for 12" OEC/GE 9800_Sterile_50ea/cs
46-CARM20-S	X-Ray Drape_54x64in_Sterile_50EA/CS
46-CARM21-S	Mini_C-ARM_DRAPE_FOR_OEC_6600_41inX84in_Sterile_50EA/CS
46-CARM22-S	Mini_C-ARM_DRAPE_FOR_OEC_68000_54inX84in_Sterile_50EA/CS
44-0596P-S	Video Camera Drape_w/perforated tip_5inx96in_Sterile_50ea/cs
44-0796P-S	Video Camera Drape_w/perforated tip_7inx96in_Sterile_50ea/cs
44-0996P-S	Camera Drape_9"x96" _25ea/cs
44-0596PV-S	Video Camera Drape_w/perforated tip_5inx96in_25ea/cs
44-0796PV-S	Video Camera Drape_w/paperboard_w/perforated tip_7inx96in_Sterile_50ea/cs
44-0596PR-S	Video cover ring-folded_25ea/cs
44-0796E-S	Camera Drape_7inx96in_latex_free_bulk_25ea/cs
44-0596E-S	Camera_Drape_5inx96in_latex_free_bulk_25ea/cs
44-0996E-S	Camera_Drape_9inx96inlatex_free_bulk_25ea/cs
44-0796EV-S	Camera Drape_7inx96in_latex_free_bulk_50ea/cs

44-0596EV-S	Video Camera Drape_5inx96in_25ea/cs
44-0596ER-S	Video cover ring-folded_25ea/cs
41-4470-S	COVER_SETUP 44W X 70L_Sterile_CLEAR_40ea/cs
41-4477-S	COVER_SETUP 44W X 77L_Sterile_CLEAR_40ea/cs
41-4490-S	COVER_SETUP 44W X 90L_Sterile_CLEAR_25ea/cs
41-5470-S	COVER_SETUP 54W X 70L_Sterile_CLEAR_25ea/cs
41-5480-S	COVER_SETUP 54W X 80L_Sterile_CLEAR_40ea/cs
41-5490-S	COVER_SETUP 54W X 90L_Sterile_CLEAR_15ea/cs
46-CAS2024-S	X-Ray Cassette Cover_Medium_Cuffed with Adhesive Closure_20 in x 24 in_Sterile_50EA/CS
46-CAS2425-S	X-Ray Cassette Cover_Large_Cuffed with Adhesive Closure_24 in x 25 in_Sterile_50EA/CS
46-CAS2024L-S	X-Ray Cassette Cover_Medium_Cuffed with Release Liner_20 in x 24 in_Sterile_50EA/CS
46-CAS2425L-S	X-Ray Cassette Cover_Large_Cuffed with Release Liner_24 in x 25 in_Sterile_50EA/CS
46-CAS2440D-S	X-Ray Cassette Cover_Large_Double Cuffed_24 in x 40 in_Sterile_50EA/CS
46-KB2636-S	Keyboard_Cover_26inx36in_Sterile_50EA/CS
46-RC411-S	Remote_Control_Cover_4inx11in_Sterile_50EA/CS
46-RC714-S	Remote_Control_Cover_7inx14in_Sterile_50EA/CS
40-3020-S	Band Bag with Tape and Rubberbands_30inx20in_Sterile_25ea/cs
40-3028-S	Band Bag with Tape and Rubberbands_30inx28in_bulk_Sterile_25ea/cs
40-3030-S	Band Bag with Tape and Rubberbands_30inx30in_Sterile_25ea/cs
40-3036-S	Band Bag with Tape and Rubberbands_30inx36in_Sterile_25ea/cs
40-3040-S	Band Bag with Tape and Rubberbands_30inx40in_bulk_Sterile_25ea/cs
40-3612-S	Band Bag with Tape and Rubberbands_36inx12in_bulk_Sterile_25ea/cs
40-3620-S	Band Bag with Tape and Rubberbands_36inx20in_Sterile_25ea/cs
40-3628-S	Band Bag with Tape and Rubberbands_36inx28in_Sterile_25ea/cs
40-3630-S	Band Bag with Tape and Rubberbands_36inx30in_Sterile_25ea/cs
40-3636-S	Band Bag with Tape and Rubberbands_36inx36in_Sterile_25ea/cs
40-3640-S	Band Bag with Tape and Rubberbands_36inx40in_Sterile_25ea/cs
40-3650R-S	Band Bag with Tape and Rubberbands_36inx50in_Sterile_with rubberbands_25ea/cs
40-3650-S	Band Bag with Tape and Rubberbands_36inx50in_Sterile_25ea/cs
40-3654R-S	Band Bag with Tape and Rubberbands_36inx54in_Sterile_with rubberbands_25ea/cs
40-3654-S	Band Bag with Tape and Rubberbands_36inx54in_Sterile_25ea/cs
40-4020-S	Band Bag with Tape_Sewn Elastic_40inx20in_Sterile_25ea/cs
40-4030-S	Band Bag with Tape_Sewn Elastic_40inx30in_Sterile_25ea/cs
40-4036-S	Band Bag with Tape_Sewn Elastic_40inx36in_Sterile_25ea/cs
40-4040-S	Band Bag with Tape_Sewn Elastic_40inx40in_Sterile_25ea/cs
46-CARM25-2S	C-ARM cover large_Sterile_20 pouches(40ea/cs)
0030-S	Banded bag_sew with elastic_30in circular_Sterile_50ea/cs
0052-S	Banded bag_Depth 26in_sterile_50ea/cs
26-1003-S	Isolation Bag Clear with Drawstring_20"X20"(50X50cm)_Sterile_50EA/CS
40-0030C-S	Band Bag_Dome Style_sewn elastic_30in circular_Sterile_25ea/cs
40-L7708438-S	Intensifier cover_nose-type EL_Large_Sterile_50ea/cs
40-L9111559-S	Intensifier cover_nose-type EL_XX-Large_Sterile_50ea/cs

40-L9409037-S	Intensifier cover_nose-type EL_X-Large_Sterile_50ea/cs
44-0596C-S	Camera Drape_Closed_7inx96in(18cmx244cm)_sterile_25ea/cs
44-0596PRC-S	Video cover ring-folded_25ea/cs
44-06120SE-S	Video Camera Cover/Laser Drape_6"x 120" (15cm x 306cm)_surged elastic opening_sterile_40EA/CS
44-0796C-S	Camera Drape_with closed_7inx96in_25ea/cs
44-0796CC-S	Video Camera Cover/Laser Drape_7"x96" (18cm x 244cm) _close system coupler (PU material) _Sterile_20EA/CS
46-CARM23-S	C-Arm Pack_Mini for OEC 6600_Sterile_50ea/cs
46-CARM24-S	C-Arm Pack_Mini for OEC 6800_Sterile_50ea/cs
46-CARM7C-S	X-Ray Drape_59x104in_Sterile_25EA/CS
46-RB101C-S	Robot Cover_For robotic hip tracking_Sterile_20EA/CS
46-RB102C-S	Robot Cover_For robotic knee tracking_Sterile_20EA/CS
46-RC714V-S	Remote_Control_Cover_7x14in_Sterile_50EA/CS
47-DS0365-S	Dental_Sleeve_with_Insert_Assist_Ring_2.375" X 65"_(60mm X 1650mm)_Sterile_100EA/CS
80-13506-S	Ring Basin Liner / Basin Stand Cover_Single_Single folded_Sterile_30ea/cs
80-13509-S	Ring Basin Liner / Basin Stand Cover_Double_Single folded_S 30ea/cs
E40-0014-S	Biodegradable Band Bag_Dome Style_sewn elastic_14in circular_Sterile_25ea/cs
E40-0018-S	Biodegradable Band Bag_Dome Style_sewn elastic_18in circular_Sterile_25ea/cs
E40-0020-S	Biodegradable Band Bag_Dome Style_sewn elastic_20in circular_Sterile_50ea/cs
E40-0022-S	Biodegradable Band Bag_Dome Style_sewn elastic_22in circular_Sterile_25ea/cs
E40-0026-S	Biodegradable Band Bag_Dome Style_sewn elastic_26in circular_Sterile_25ea/cs
E40-0027-S	Biodegradable Band Bag_Dome Style_sewn elastic_27in circular_Sterile_25ea/cs
E40-0030-S	Biodegradable Band Bag_Dome Style_sewn elastic_30in circular_Sterile_25ea/cs
E40-0040-S	Biodegradable Band Bag_Dome Style_sewn elastic_40 in circular_Sterile_25ea/cs
E40-0050-S	Biodegradable Band Bag_Dome Style_sewn elastic_50 in circular_Sterile_25ea/cs
E40-0060-S	Biodegradable Band Bag_Dome Style_sewn elastic_60 in circular_Sterile_25ea/cs
E40-2812-S	Biodegradable Bag with Tape and Rubberbands_28inx12in_Sterile_25ea/cs
E40-3020-S	Biodegradable Band Bag with Tape and Rubberbands_30inx20in_Sterile_25ea/cs
E40-3030-S	Biodegradable Band Bag with Tape and Rubberbands_30inx30in_Sterile_25ea/cs
E40-3036-S	Biodegradable Band Bag with Tape and Rubberbands_30inx36in_Sterile_25ea/cs
E40-3620-S	Biodegradable Band Bag with Tape and Rubberbands_36inx20in_Sterile_25ea/cs
E40-3628-S	Biodegradable Band Bag with Tape and Rubberbands_36inx28in_Sterile_25ea/cs
E40-3630-S	Biodegradable Band Bag with Tape and Rubberbands_36inx30in_Sterile_25ea/cs
E40-3636-S	Biodegradable Band Bag with Tape and Rubberbands_36inx36in_Sterile_25ea/cs
E40-3640-S	Biodegradable Band Bag with Tape and Rubberbands_36inx40in_Sterile_25ea/cs
E40-3650-S	Biodegradable Band Bag with Tape and Rubberbands_36inx50in_Sterile_25ea/cs
E40-3650R-S	Biodegradable Band Bag with Tape and Rubberbands_36inx50in_Sterile_with rubberbands_25ea/cs
E40-3654-S	Biodegradable Band Bag with Tape and Rubberbands_36inx54in_Sterile_25ea/cs
E40-3654R-S	Biodegradable Band Bag with Tape and Rubberbands_36inx54in_Sterile_with rubberbands_25ea/cs

E40-4020-S	Biodegradable Band Bag with Tape_Sewn Elastic_40inx20in_Sterile_25ea/cs
E40-4030-S	Biodegradable Band Bag with Tape_Sewn Elastic_40inx30in_Sterile_25ea/cs
E40-4040-S	Biodegradable Band Bag with Tape_Sewn Elastic_40inx40in_Sterile_25ea/cs
E40-4436-S	Biodegradable Band Bag with Tape_Sewn Elastic_44inx36in_Sterile_25ea/cs
E40-5030-S	Biodegradable Band Bag with Tape_Sewn Elastic_50inx30in_Sterile_25ea/cs
E40-5040-S	Biodegradable Band Bag with Tape_Sewn Elastic_50inx40in_Sterile_25ea/cs
ECNW001C-S	Equipment Cover_A_33x36in_sterile_100ea/cs
K62/98515	COVER CAMERA 16 X 300CM_Sterile_100ea/cs
K62/98516	COVER CAMERA 15 X 250CM_Sterile_100ea/cs
i40-0014-S	Banded bag_sew with elastic_dome14in circular_Sterile_25ea/cs
i40-0018-S	Banded bag_sew with elastic_dome18in circular_Sterile_25ea/cs
i40-0022-S	Banded bag_sew with elastic_dome22in circular_Sterile_25ea/cs
i40-0026-S	Banded bag_sew with elastic_dome26in circular_Sterile_25ea/cs
i40-0027-S	Banded bag_sew with elastic_dome27in circular_Sterile_25ea/cs
i40-0030-S	Banded bag_sew with elastic_dome30in circular_Sterile_25ea/cs
i40-0040-S	Banded bag_sew with elastic_dome 40 in circular_Sterile_25ea/cs
i40-0050-S	Banded bag_sew with elastic_dome 50 in circular_Sterile_25ea/cs
i40-2812-S	Banded bag_heatseal_w/rubberband&tape_28inx12in_Sterile_25ea/cs
i40-3020-S	Banded bag_heatseal_w/rubberband&tape_30inx20in_Sterile_25ea/cs
i40-3030-S	Banded bag_heatseal_w/rubberband&tape_30inx30in_Sterile_25ea/cs
i40-3036-S	Banded bag_heatseal_w/rubberband&tape_30inx36in_Sterile_25ea/cs
i40-3620-S	Banded bag_heatseal_w/rubberband&tape_36inx20in_Sterile_25ea/cs
i40-3628-S	Banded bag_heatseal_w/rubberband&tape_36inx28in_Sterile_25ea/cs
i40-3630-S	Banded bag_heatseal_w/rubberband&tape_36inx30in_Sterile_25ea/cs
i40-3636-S	Banded bag_heatseal_w/rubberband&tape_36inx36in_Sterile_25ea/cs
i40-3640-S	Banded bag_heatseal_w/rubberband&tape_36inx40in_Sterile_25ea/cs
i40-3650-S	Banded bag_heatseal_w/rubberband&tape_36inx50in_Sterile_25ea/cs
i40-3650R-S	Banded bag_heatseal_w/rubberband&tape_36inx50in_Sterile_with rubberbands_25ea/cs
i40-3654-S	Banded bag_heatseal_w/rubberband&tape_36inx54in_Sterile_25ea/cs
i40-3654R-S	Banded bag_heatseal_w/rubberband&tape_36inx54in_Sterile_with rubberbands_25ea/cs
i40-4020-S	Banded bag_heatseal_w/rubberband&tape_40inx20in_Sterile_25ea/cs
i40-4030-S	Banded bag_heatseal_w/rubberband&tape_40inx30in_Sterile_25ea/cs
i40-4040-S	Banded bag_heatseal_w/rubberband&tape_40inx40in_Sterile_25ea/cs
i40-5030-S	Banded bag_heatseal_w/rubberband&tape_50inx30in_Sterile_25ea/cs
i40-5040-S	Banded bag_heatseal_w/rubberband&tape_50inx40in_Sterile_25ea/cs
i46-CARM11-S	Fluorscope Drape_36" x 44" _sterile_package_160ea/cs
i46-CARM12-S	X-ray Image Intensifier Drape_64" x 41" _sterile_package_60ea/cs
i80-13506-S	Ring Basin Liner / Basin Stand Cover_Single_Single folded_Sterile_30ea/cs
i80-13509-S	Ring Basin Liner / Basin Stand Cover_Double_Single folded_S 30ea/cs
40-8085B-S	Protective Shield Cover_L-Shape_Large_Sterile_50ea/cs
40-9092B-S	Protective Shield Cover_L-Shape_X-Large_Sterile_50ea/cs
40-90117B-S	Protective Shield Cover_L-Shape_XX-Large_Sterile_50ea/cs