

EU DECLARATION OF CONFORMITY BY MANUFACTURER

We, **S. Jee Enterprises** With registered place of business at **CANTT ROAD, Sialkot-51310-Pakistan** being manufacturer declare that the detailed below medical devices of above mentioned manufacturer fulfilled the requirements specified in the Medical Device Regulation (MDR) 2017/745 dated May 05, 2017 and applicable Harmonized Standard(s) / Common Specifications (CS). This EU Declaration of Conformity has been issued under our sole responsibility.

Manufacturer SRN: PK-MF-000043969

Detail of the Products:

Basic UDI-DI	Cat No.	Classification	Classification Rule & justification	Product and Trade Name	Intended Purpose
8964002454143	IV-1114-202	Class I	1 Non-invasive, Non-Active, non-sterile, non-measuring	IV STAND S/S AISI 202 ANTISTATIC WHEELS	Mobile stand for infusion therapy; intravenous administration of fluids/solutions or blood transfusions. The intravenous bags are hung from the hooks at the top of the stand.
8964002454143	IV-1114-SPEC	Class I	1 Non-invasive, Non-Active non-sterile, non-measuring	IV STAND Premium - Single hand operating on caster- ANTISTATIC WHEELS- AISI 202	Mobile stand for infusion therapy; intravenous administration of fluids/solutions or blood transfusions. The intravenous bags are hung from the hooks at the top of the stand.
8964002454068	SJ-200-001	Class I	1 Non-invasive, Non-Active non-sterile, non-measuring	S/S I.V. BASKET - AISI 304	It keeps intravenous bags full of medicine or fluid in place.
8964002454129	WBD-4214-SI	Class I	1 Non-invasive, Non-Active non-sterile, non-measuring	TROLLEY WITH 1 BASIN -4lt- AISI 202	Mobile stand with single bowl for surgery..
8964002454129	WBD-4214-GM	Class I	1 Non-invasive, Non-Active non-sterile, non-measuring	TROLLEY WITH 2 BASINS - capacity 4l each -AISI 202	Mobile stand with double bowl for surgery.
8964002454112	SJ-70-003	Class I	1 Non-invasive, Non-Active non-sterile, non-measuring	BASIN capacity 4lt- AISI 304	Used to hold swabs and waste products from the operation.
8964002454044	SJ-14-004 SJ-14-007 SJ-14-25126 SJ-14-30156 SJ-14-502010 SJ-14-005 SJ-14-006	Class I	1 Non-invasive, Non-Active non-sterile, non-measuring	S/S BOX WITHOUT HANDLES Type: D – AISI 202 18x8x4 CM 20x10x 6 CM 25x12x 6 CM 30x15x 6 CM 50x20x10 CM 20X10X4 CM 20X10X5 CM	For surgical instrument storage.



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8964002454044	SJ-18-006 SJ-18-007 SJ-18-502010 SJ-18-004 SJ-18-20104 SJ-18-25124 SJ-18-30156	Class I	1 Non-invasive, Non-Active non-sterile, non-measuring	S/S BOX WITH HANDLES Type: D – AISI 202 20X10X5 CM 20X10X6 CM 50X20X10 CM 18X8X4 CM 20X10X4,5 CM 25X12,5X4,6 CM 30X15X 6 CM	For surgical instrument storage.
8964002454105	SJ-72-003 SJ-72-004 SJ-72-005 SJ-72-008	Class I	1 Non-invasive, Non-Active non-sterile, non-measuring	GALIPOTS WITH SPOUT - AISI 202 - 0.6 THICK 60X30 MM 80X40 MM 100X50 MM 150X65 MM	Used to mix medications or compounds during procedures
8964002454112	SJ-25-006 SJ-25-009 SJ-25-010 SJ-25-014 SJ-25-017 SJ-25-021	Class I	1 Non-invasive, Non-Active non-sterile, non-measuring	INSTRUMENT TRAY TYPE:D - AISI 202 - 0.6 THICK 200X150X40 MM 220X150X30 MM 220X150X50 MM 250X200X50 MM 300X210X40 MM 350X260X40 MM	Provide a suitable platform for placing/containing surgical instruments during a clinical procedure.





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8964002454051	SJ-61-001G SJ-61-003G SJ-61-004G SJ-61-006G	Class I	1 Non-invasive, Non-Active non-sterile, non-measuring	Kidney dish Gold AISI 202 - plasma coating 6" – 200 ML 8" – 500 ML 10" -800 ML 12"- 1500 ML	Used in surgical procedure for carrying dressing, bandages, small instruments, soiled dressing and medical waste.
8964002454051	SJ-61-001 SJ-61-003 SJ-61-004 SJ-61-006	Class I	1 Non-invasive, Non-Active non-sterile, non-measuring	KIDNEY TRAY GERMAN PATTERN TYPE:B - AISI 202 0,5 THICK 6" – 200 ML 8" – 500 ML 10" -800 ML 12"- 1500 ML	Used in surgical procedure for carrying dressing, bandages, small instruments, soiled dressing and medical waste.
8964002454051	SJ-63-003 SJ-63-004 SJ-63-006	Class I	1 Non-invasive, Non-Active non-sterile, non-measuring	KIDNEY TRAY DELUXE TYPE:D AISI 202 0,6 THICK 8" – 500 ML 10" -800 ML 12"- 1500 ML	Used in surgical procedure for carrying dressing, bandages, small instruments, soiled dressing and medical waste.
8964002454075	SJ-32-004 SJ-32-003 SJ-32-1612 SJ-32-1924 SJ-32-005 SJ-32-011 SJ-32-1916 SJ-32-010 SJ-32-012 SJ-32-2916 SJ-32-015 SJ-32-021 SJ-32-3925 SJ-32-016 SJ-32-019 SJ-32-3418	Class I	1 Non-invasive, Non-Active non-sterile, non-measuring	S/S STERILISING DRUM DRUM 150X150 MM 150X100 MM 165X120 MM 190X240 MM 180X180 MM 240X190 MM 190X160 MM 240X160 MM 240X240 MM 290X160 MM 290X240 MM 340X340 MM 390X250 MM 290X290 MM 340X240 MM 340X180 MM	Used to sterilize dressing materials, surgical instruments, surgical towels, in a steam sterilizer (autoclave).
8964002454082	SJ-110-25245 SJ-110-25247 SJ-110-252410 SJ-110-40255 SJ-110-40257 SJ-110-402510 SJ-110-54255 SJ-110-54257 SJ-110-542510 SJ-118-25245 SJ-118-25246 SJ-118-48255 SJ-118-48256 SJ-118-48485 SJ-118-48486	Class I	1 Non-invasive, Non-Active non-sterile, non-measuring	S/S WIRE MESH BASKET 255x245x50 mm 255x245x70 mm 255x245x100 mm 405x255x50 mm 405x255x70 mm 405x255x100 mm 540x255x50 mm 540x255x70 mm 540x255x100 mm 250X240X50mm 250X240X60mm 480X250X50mm 480X250X60mm 480X480X50mm 480X480X60mm	Used for washing, sterilization, storage and transportation of instruments.
8964002454099	SJ-56-003	Class I	1 Non-invasive, Non-Active non-sterile, non-measuring	Urinal 114x220mm-ltr.1,5 diagonal (inclined)	For urination only.



We further declare that we have designated the following company as our Sole Authorized Representative in EU as required by Article 11 of the MDR 2017/745:

KHANG BAO INTERNATIONAL KFT
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SRN: HU-AR-000034102

Also we have written contract with above stated authorized representative which include necessary mandate for him. He has accepted the mandate in write

For **S. Jee Enterprises**

Signature 
Name: Mohsan Raza
Position QA Manager
Place: Sialkot Date: 30.01.2025