



EC Certificate

Production Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V

(Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 047330 0061 Rev. 00

Manufacturer

FIRSTAR HEALTHCARE COMPANY LIMITED (GUANGZHOU)

Rm.901
Building No.2, Headquarters Center
Tian'an High-tech Ecological Park
Panyu
511400 Guangzhou
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies):

Sterile Gauze Sponges, Gauze Rolls, Sterile Non-woven Sponge, Wound Dressing, Sterile Non-adhesive Dressing, Sterile Eye Pad, First Aid Kit, Sterile Plaster Strips, Sterile First Aid Dressing Bandages, Urine Bag, Single Use Oral Syringes, Abdominal Pads, Eye Wash, Skin Closures, Alcohol Pad, Surgical Mask

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:G2S 047330 0061 Rev. 00](http://www.tuvsud.com/ps-cert?q=cert:G2S_047330_0061_Rev_00)

Report No.: SH2118101

Valid from: 2021-05-06

Valid until: 2024-05-26

Date, 2021-05-06

Christoph Dicks
Head of Certification/Notified Body

Establishment Registration & Device Listing

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1 result found for **Establishment Registration**
or **Business Trade Name** : *firstar*
Establishment Registration or FEI Number :
3003887292

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| Establishment Name | Registration Number | Current Registration Yr |
|--|---------------------|---|
| FIRSTAR HEALTHCARE Company Limited (Guangzhou) CHINA | 3003887292 | 2021 |
| Tape And Bandage, Adhesive - ADHESIVE BANDAGE: Band Aid, FIRSTAR STRIPS, Inject-Safe Bandage | | Contract Manufacturer; Foreign Exporter; Manufacturer; Repackager/Relabeler |
| Mouthpiece, Breathing - FIRSTAR MOUTH TO MOUTH SHIELD | | Contract Manufacturer; Manufacturer |
| Bandage, Elastic - Firstar | | Foreign Exporter; Repackager/Relabeler |
| Apparatus, Suction, Single Patient Use, Portable, Nonpowered - FIRSTAR RESERVOIR KIT: WOUND DRAINAGE RESERVOIR | | Foreign Exporter |
| Scissors, Medical, Disposable - FIRSTAR | | Foreign Exporter |
| Gauze / Sponge, Nonresorbable For External Use - FIRSTAR | | Foreign Exporter |
| Forceps - FIRSTAR | | Foreign Exporter |
| Bandage, Cast - FIRSTAR TRIANGLE BANDAGE | | Repackager/Relabeler |
| Applicator, Absorbent Tipped, Non-Sterile - FIRSTAR SWAB STICK | | Foreign Exporter |
| Garment, Protective, For Incontinence - BLANKET | | Foreign Exporter |
| First Aid Kit Without Drug - EMPTY FIRST AID BOX: FIRSTAR FIRST AID KITS | | Contract Manufacturer; Manufacturer |
| Dressing, Wound, Hydrophilic - First Aid Bandage: FIRSTAR First Aid Dressing | | Foreign Exporter; Repackager/Relabeler |
| Reminder, Medication - 7 Days Pill Box: Reminder Pill Box | | Foreign Exporter |
| Vinyl Patient Examination Glove - PVC Glove; VINYL Glove | | Foreign Exporter |
| Thermometer, Electronic, Clinical - Clinical Electronic Thermometer | | Foreign Exporter |
| Cover, Cast - Cast And Bandage Protector | | Manufacturer |
| Extractor, Vein - Venimex Pump | | Manufacturer |
| Cannula, Nasal, Oxygen - Plastic Tubing | | Foreign Exporter |
| Polymer Patient Examination Glove - Powder-Free Nitrile Examination Gloves | | Foreign Exporter |
| Pads, Menstrual, Scented-Deodorized - Firstar Underpad | | Foreign Exporter |
| First Aid Kit With Drug - First Aid Kit With Drug | | Contract Manufacturer |
| Pill Crusher/Cutter - Pill Cutter | | Contract Manufacturer |
| Pack, Hot Or Cold, Disposable - INSTANT COLD PAC | | Foreign Exporter |
| Nasal Spray, Ent Delivery - Inhaler | | Contract Manufacturer |
| Fiber, Medical, Absorbent - Abdominal Combine Pads | | Foreign Exporter |
| Pad, Eye - Eye Pad | | Foreign Exporter |
| Shield, Protective, Personnel - Isolation Face Shield, Isolation Face Mask, Medical Face Shield, Medical Shield, Face Shield | | Manufacturer |
| Mask, Surgical - Surgical Masks | | Foreign Exporter; Repackager/Relabeler |
| Face Mask Per Enforcement Policy For Face Masks And Respirators During The Declared Public Health Emergency - Face Mask, Disposable Face Mask, Disposable Mask, Disposable Protective Mask | | Contract Manufacturer; Foreign Exporter; Manufacturer |
| Respirator, Surgical - KN95 Respirator, KN95 Mask, Face Mask, Particulate Respirator | | Contract Manufacturer; Foreign Exporter; Manufacturer |
| Accessory, Surgical Apparel - Face Shield, Isolation Face Shield, Isolation Mask | | Foreign Exporter; Manufacturer |
| Non-Surgical Isolation Gown - Isolation Gown | | Contract Manufacturer; Foreign Exporter; Manufacturer |
| Body Fluid Clean Up Kit - Spill Kit | | Manufacturer |
| Cover, Shoe, Operating-Room - Disposable Shoe Cover | | Manufacturer |
| Spill Kit - Spill Kit | | Manufacturer |
| Valve, Non-Rebreathing - CPR Face Shield | | Manufacturer |
| Valve, Non-Rebreathing - Pocket Mask, CPR Mask, E Mask | | Manufacturer |

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Page Last Updated: 07/12/2021

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U.S. Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA



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Certificate

No. Q6 047330 0050 Rev. 04

Holder of Certificate: **FIRSTAR HEALTHCARE
COMPANY LIMITED (GUANGZHOU)**

Rm.901
Building No.2, Headquarters Center
Tian'an High-tech Ecological Park
Panyu
511400 Guangzhou
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate:

Production and Distribution of Sterile First Aid Dressing Bandages, Sterile Hemostasis Adhesive Dressing, Gloves, Medical Tape and Strip, Surgical Dressing, Infusion System, Blood Taking System, Thermometers, First Aid Kit, Surgical Needles, Silk Suture, Wound Drainage Reservoir, Cold Pack, Condom, Surgical Blades and Lancet, Sphygmomanometer, Emergency Equipment, Disposable Medical Plastic Products, Masks, Waterproof Protectors, Medical Cup, Foam Dressing, Arm Sling, Medical Tapes, Resuscitator, Basic Dressing Pack, Finger Splint, Tactical Tourniquet, Cervical Collar, Nose Cleaner, Sterile Syringes with Needle for Single Use, Medical Splint, Kinesio Tape, Venom Extractor Kit, Self-adhesive Elastic Bandage for Medical, Warmers, Abdominal Pads, Wound Dressing, Single Use Oral Syringes, Inject Safe Barrier Bandage, Alcohol Pads, Eye Wash, Cotton Roll, Non-Sterile Tongue Depressor, Stretcher, Skin Closures, Isolation Gown, Surgical Mask

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system (excluding subclause 7.3), which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q6_047330_0050_Rev._04

Report No.: SH2018104
Valid from: 2021-03-24
Valid until: 2023-08-31

Date, 2021-03-24

Christoph Dicks
Head of Certification/Notified Body

Certificate

No. Q6 047330 0050 Rev. 04

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

**FIRSTAR HEALTHCARE COMPANY LIMITED
(GUANGZHOU)**
Rm.901, Building No.2, Headquarters Center, Tian'an
High-tech Ecological Park, Panyu, 511400 Guangzhou,
PEOPLE'S REPUBLIC OF CHINA

Distribution of Sterile First Aid Dressing Bandages, Sterile Hemostasis Adhesive Dressing, Gloves, Medical Tape and Strip, Surgical Dressing, Infusion System, Blood Taking System, Thermometers, First Aid Kit, Surgical Needles, Silk Suture, Wound Drainage Reservoir, Cold Pack, Condom, Surgical Blades and Lancet, Sphygmomanometer, Emergency Equipment, Disposable Medical Plastic Products, Masks, Waterproof Protectors, Medical Cup, Foam Dressing, Arm Sling, Medical Tapes, Resuscitator, Basic Dressing Pack, Finger Splint, Tactical Tourniquet, Cervical Collar, Nose Cleaner, Sterile Syringes with Needle for Single Use, Medical Splint, Kinesio Tape, Venom Extractor Kit, Self-adhesive Elastic Bandage for Medical, Warmers, Abdominal Pads, Wound Dressing, Single Use Oral Syringes, Inject Safe Barrier Bandage, Alcohol Pads, Eye Wash, Cotton Roll, Non-Sterile Tongue Depressor, Stretcher, Skin Closures, Isolation Gown, Surgical Mask

FIRSTAR MEDICAL INDUSTRIAL LTD.
No.4-5, 2nd Industrial District, Dongshen Cun Dongchong
Town, Nansha, 511475 Guangzhou, PEOPLE'S REPUBLIC
OF CHINA

Production of Sterile First Aid Dressing Bandages, Sterile Hemostasis Adhesive Dressing, Gloves, Medical Tape and Strip, Surgical Dressing, Infusion System, Blood Taking System, Thermometers, First Aid Kit, Surgical Needles, Silk Suture, Wound Drainage Reservoir, Cold Pack, Condom, Surgical Blades and Lancet, Sphygmomanometer, Emergency Equipment, Disposable Medical Plastic Products, Masks, Waterproof Protectors, Medical Cup, Foam Dressing, Arm Sling, Medical Tapes, Resuscitator, Basic Dressing Pack, Finger Splint, Tactical Tourniquet, Cervical Collar, Nose Cleaner, Sterile Syringes with Needle for Single Use, Medical Splint, Kinesio Tape, Venom Extractor Kit, Self-adhesive Elastic Bandage for Medical, Warmers, Abdominal Pads, Wound Dressing, Single Use Oral Syringes, Inject Safe Barrier Bandage, Alcohol Pads, Eye Wash, Cotton Roll, Non-Sterile Tongue Depressor, Stretcher, Skin Closures, Isolation Gown, Surgical Mask