ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 024761 0166 Rev. 05

Holder of Certificate: **JMS CO., LTD.**
12-17 Kako-machi, Naka-ku
Hiroshima-shi, Hiroshima
730-8652 JAPAN

Certification Mark:

TÜV SÜD EN ISO 13485 tuvsud.com/ps-cert

Scope of Certificate:

Design and Development, Production, and Distribution of Sterile A.V.Fistula Needles, Injection Syringes, Serum Collection Set, Intravascular Catheter, Extension Tube, Stopcock, Transfusion Set, Connector and Cap for Infusion / Transfusion and Dialysis, Infusion Set, Enteral Nutrition Set, Blood Circuit Extension Tube, Haemodialyser / Haemodiafilter / Haemofilter / Haemoconcentrator, Arterial Cannulae, Peritoneal Dialysis Catheter, Peritoneal Dialysis Catheterization Kit, Peritoneal Dialysis Tubing & Exchanging Set, Injection / Blood-Collection / Aspiration Needles, Blood Circuits for Plasma Separation, Suction Kits, Vein Strippers & Kits, Central Venous Micro Catheters & Kits, Heat Exchangers, Membrane Oxygenerators, Hard Shell Reservoirs, Arterial Blood Filters, Suction Tips, Heart-Lung Bypass Unit Tubing Sets, Closed System Transfer Device, Suture Passer, Infusion Adaptor, Connecting Tube for Infusion, Enteral Nutrition Syringes, Dialysis Start / Stop Set, and Carpal Tunnel Syndrome Device, and of Non-sterile Dialysate Multipatient Delivery Machines, Pressure Measuring Units for Artificial Cardiopulmonary Tubing Sets, and Oral or Swallowing Function Related Devices.
Design and Development, and Distribution of Non-sterile Haemodialysis Equipment.
Distribution of Sterile Surgical Gloves, Non-powdered Latex Surgical Gloves, and Polychloropren Surgical Gloves, and of Non-sterile Syringe Pump.

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 024761 0166 Rev. 05

Report No.: JN200350000266

Valid from: 2024-06-01
Valid until: 2027-05-31

Date, 2024-05-29

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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Applied Standard(s):

ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems - Requirements for regulatory purposes

Facility(ies):

JMS CO., LTD. Miyoshi Plant
350 Yamaga, Shijikkan-machi, Miyoshi-shi, Hiroshima, 728-0016 JAPAN

Design and Development, and Production of Sterile A.V.Fistula Needles, Injection Syringes, Intravascular Catheter, Connector and Cap for Infusion / Transfusion and Dialysis, Infusion Set, Enteral Nutrition Set, Blood Circuit Extension Tube, Arterial Cannulae, Peritoneal Dialysis Catheter, Injection / Blood-Collection / Aspiration Needles, Blood Circuits for Plasma Separation, Suction Kits, Vein Strippers & Kits, Infusion Adaptor, Connecting Tube for Infusion, Enteral Nutrition Syringes and Carpal Tunnel Syndrome Device.
Production of Non-sterile Oral or Swallowing Function Related Devices.

JMS CO., LTD. Izumo Plant
127-1 Shimokoshi-cho, Izumo-shi, Shimane, 693-0032 JAPAN

Design and Development, Production, and Distribution of Sterile Serum Collection Set, Extension Tube, Stopcock, Transfusion Set, Connector and Cap for Infusion / Transfusion and Dialysis, Infusion Set, Enteral Nutrition Set, Arterial Cannula, Peritoneal Dialysis Tubing & Exchanging Set, Central Venous Micro Catheters and Kits, Heat Exchangers, Membrane Oxygenerators, Hard Shell Reservoirs, Arterial Blood Filters, Suction Tips, Heart-Lung Bypass Unit Tubing Sets, Closed System Transfer Device, and Enteral Nutrition Syringes.
Design and Development, and Production of Sterile Peritoneal Dialysis Catheterization Kit, and Dialysis Start / Stop Set.

JMS CO., LTD. Chiyoda Plant
10 Shinujigami, Kitahiroshima-cho, Yamagata-gun, Hiroshima, 731-1514 JAPAN

Design and Development, Production, and Distribution of Sterile Haemodialyser / Haemodiafilter / Haemofilter / Haemoconcentrator, Central Venous Micro Catheters & Kits, and Suture Passer, and of Non-sterile Dialysate Multipatient Delivery Machines, and Pressure Measuring Units for Artificial Cardiopulmonary Tubing Sets.
Production and Distribution of Sterile A.V.Fistula Needles, Injection Syringes, Connector and Cap for Infusion / Transfusion and Dialysis, Infusion Set, Enteral Nutrition Set, Enteral Nutrition Syringes, Blood Circuit Extension Tube, Arterial Cannulae, Peritoneal Dialysis Catheter, Injection / Blood-Collection / Aspiration Needles, Blood Circuits for Plasma Separation, Suction Kits, Peritoneal Dialysis Catheterization Kit, Intravascular Catheter, Vein Strippers & Kits, Infusion Adaptor, Connecting Tube for

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Infusion, Dialysis Start / Stop Set, and Carpal Tunnel Syndrome Device.
Distribution of Sterile Surgical Gloves, Non-powdered Latex Surgical Gloves, and Polychloropren Surgical Gloves, and of Non-sterile Syringe Pump, Oral or Swallowing Function Related Devices, and Haemodialysis Equipment.

JMS CO., LTD. Hiroshima Headquarters

12-17 Kako-machi, Naka-ku, Hiroshima-shi, Hiroshima, 730-8652 JAPAN

Design and Development, Production, and Distribution of Sterile A.V.Fistula Needles, Injection Syringes, Serum Collection Set, Intravascular Catheter, Extension Tube, Stopcock, Transfusion Set, Connector and Cap for Infusion / Transfusion and Dialysis, Infusion Set, Enteral Nutrition Set, Blood Circuit Extension Tube, Haemodialyser / Haemodiafilter / Haemofilter / Haemoconcentrator, Arterial Cannulae, Peritoneal Dialysis Catheter, Peritoneal Dialysis Catheterization Kit, Peritoneal Dialysis Tubing & Exchanging Set, Injection / Blood-Collection / Aspiration Needles, Blood Circuits for Plasma Separation, Suction Kits, Vein Strippers & Kits, Central Venous Micro Catheters & Kits, Heat Exchangers, Membrane Oxygenerators, Hard Shell Reservoirs, Arterial Blood Filters, Suction Tips, Heart-Lung Bypass Unit Tubing Sets, Closed System Transfer Device, Suture Passer, Infusion Adaptor, Connecting Tube for Infusion, Enteral Nutrition Syringes, Dialysis Start / Stop Set, and Carpal Tunnel Syndrome Device, and of Non-sterile Dialysate Multipatient Delivery Machines, Pressure Measuring Units for Artificial Cardiopulmonary Tubing Sets, and Oral or Swallowing Function Related Devices.
Design and Development, and Distribution of Non-sterile Haemodialysis Equipment.
Distribution of Sterile Surgical Gloves, Non-powdered Latex Surgical Gloves, and Polychloropren Surgical Gloves, and of Non-sterile Syringe Pump.

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