EU Quality Management System Certificate

Certificate no.:
C546185

Initial certification date:
24 May 2024

Valid Until:
23 May 2029

This is to certify that the quality system of

Vitromed Healthcare

A-22 to A-27, Bais Godam Industrial Estate,
Jaipur, Rajasthan (India)-302006
SRN: IN-MF-000021420

For Design , Production and Final product inspection/ Testing of

IV Cannula (Intravenous Cannula With / Without Safety Feature), Levins Tube, Umbilical Cord Clamp, Three Way Stop Cock With And Without Extension Tubing, Extension Tube, Nelaton Catheter, Female Catheter, Yankaur Suction Set (Suction Tube And Handle), Measured Volume Fluid Administration Set, High Pressure Vacuum Drainage Bottle With And Without Trocar, Rectal Catheter, Urine Bag With And Without Measured Volume Meter, Foley Balloon Catheter, Scalp Vein Set (Winged Infusion) With And Without Safety Feature, Blood Transfusion Set, Redon Drainage Tubes, Thoracic Drainage Catheter, Flow Regulators, Tur Set, Infusion Set With And Without Vent, Closed Wound Suction Unit, Mucus Extractor With /Without Bacterial Barrier Filter, Oxygen Mask, Ryles tube, Infant Feeding Tube, Guedel Airways, Nasal Oxygen Cannula, Nebulizer Mask, Suction Catheter, Stomach Tube, Oxygen Catheter, Tracheal Tube, Peritoneal Dialysis Transfusion Set, Accessories of Breathing Circuits, Under Water Sealed Drainage System, Blood Line Set, Venturi mask, Fistula Needle With /Without Safety Feature, Catheter Mount, Feeding Bag.

Has been assessed and found to comply with respect to:

The conformity assessment procedure described in Annex IX, (Chapter I & III) of Regulation (EU) 2017/745 on Medical Devices

Place and date:
Høvik, 24 May 2024

For the issuing office:
DNV Product Assurance AS – Notified Body 2460
Veritasveien 1, 1363 Høvik, Norway

Mariann Jeremiassen
Management Representative

Lack of fulfilment of conditions as set out in the Certification Agreement may render this Certificate invalid.

Certificate no.: C546185

Place and date: Høvik, 24 May 2024

Jurisdiction

Application of Regulation 2017/745 on medical devices, adopted as “Forskrift om Medisinsk Utstyr” by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Report No.	Issue Date
0.0	Original Certificate	2717404	24 May 2024

Products covered by this Certificate:

Product Description	Product Name	Class
Foley balloon catheter	Two Way & Three Way (Latex & Silicon Elastomer) 8FG, 10FG, 12FG, 14FG, 16FG, 18FG, 20FG, 22FG, 24FG	IIa
Infant feeding tube	Infant Feeding Tube with Female Mount: 4FG, 5FG, 6FG, 7FG, 8FG, 9FG, 10FG Length: 40cm, 50cm, 100cm Infant Feeding Tube with Luer Lock: 4FG, 5FG, 6FG, 7FG, 8FG, 9FG,10FG Length: 40 cm, 50cm, 100cm	IIa
Yankaur suction set (suction tube and handle)	With and without Crown and standard tip: 180 cm, 210 cm, 250 cm, 270 cm, 300 cm, 350 cm, 400 cm	IIa
Urine bag with and without measured volume meter	With 250ml & 500ml Volume Meter and 2000ml urine collection bag (100 ml, 800 ml, 2000 ml)	Is
Umbilical cord clamp	Vaso Clamp, Umbilical Cord Clamp Blue, Umbilical Cord Clamp White, Umbilical Cord Clamp Yellow	Is
Infusion set with and without vent	IV Infusion Set with Vented spike IV Infusion Set with Non-vented spike IV Infusion Set with Flow Regulator I.V. Infusion set with 3 way stop cock Micro IV Infusion Set I.V. Infusion set with Inline 0.2-micron filter I.V Infusion set with Auto stop function Infusion set with Photo fusion	IIa
Blood line set	Blood Lines, Blood Line S, Blood Line T, Blood Line Post Pump Blood Line Pre Pump	IIa
Oxygen Mask	Oxygen Mask Adult & Paediatric (Child): with/without reservoir bag 600 ml, Adult, with/ without reservoir bag 600 ml, Child	IIa
Threeway stop cock with and without extension tubing	Three Way Stop Cock with Blue Handle Three Way Stop Cock with Red Handle Three Way Stop Cock with White Handle Three Way Stop Cock with Lipid Resistant Three Way Stop Cock with Lipid Resistant 45 Degree,	IIa

	Three way Extension tube 10 cm, 15 cm, 25 cm, 50 cm, 80 cm, 100 cm, 150 cm, 200 cm, DHEP Free & PVC Free	
Thoracic drainage catheter	With trocar and right angle, without trocar and right angle Thoracic Drainage Catheter- Straight Thoracic Drainage Catheter- Angled Thoracic Drainage Catheter- Trocar 8FG, 10FG, 12FG, 14FG, 16FG, 18FG, 20FG, 22FG, 24FG 26FG, 28 FG, 30 FG, 32 FG, 36 FG, 40 FG,	IIa
Female catheter	6FG, 8FG, 10FG, 12FG, 14FG, 16FG, 18FG, 20FG, 22FG, 24FG	IIa
IV Cannula (Intravenous cannula with/without safety feature)	I.V. Cannula (Flon type), I.V. Cannula (Can type), I.V Cannula (Win type), I.V Cannula (Flex type), I.V Cannula (Cath type), I.V Cannula (Pen type), I.V Cannula (Neo type), I.V Cannula (Vitronovo type), I.V. Cannula with tubing, Vitrowin 2 IV Cannula, I.V. Cannula (Flon Rapid), Vitrocan rapid, Vitrowin Rapid, Vitroflex Rapid, Vitrocath rapid, I.V Cannula (Pen rapid), I.V Cannula (Neo rapid), Safety I.V Cannula (Flex type), Safety I.V Cannula (Can type), Safety I.V Cannula (Win type), Safety I.V Cannula (Pen type)), Safety I.V Cannula with three way stopcock, I.V Cannula (Adva win type), Safety I.V. Cannula with DEHP free extension tube 14G, 16G, 17G, 18G, 20G, 22G, 24G, 26G	IIa
Nasal oxygen cannula	Adult, Paediatric, Neonatal	IIa
Catheter mount	-	IIa
Closed wound suction unit	Vitrovac Set (600 ml & 800 ml): 6FG 8FG ,10FG, 12FG, 14FG, 16FG, 18FG. Neovac set 50ml: 6FG, 8 FG. Spring loaded Closed Wound Suction Unit (200 ml & 400 ml): 6FG 8FG,10FG, 12FG, 14FG, 16FG, 18FG.	IIa
Measured volume fluid administration set	Burette Set capacity 110 ml, Burette Set capacity-150 ml, Burette Set capacity 100 ml	IIa
Flow regulator	Flow Regulator with 20cm PVC DEHP free, PVC Free tube Flow Regulator with 40cm PVC DEHP free, PVC Free tube with Latex free "Y" injection port Flow Regulator with 40cm PVC DEHP free, PVC Free tube with thumb support Latex free "Y" injection port Flow Regulator with 40cm PVC DEHP free , PVC Free Tube with Needle free "Y" injection port	IIa
Fistula needle with/without Safety feature	Fistula Needles with fixed wings: 15G, 16G, 17G Safety Fistula Needles with rotating wings: 15G, 16G, 17G	IIa
Blood transfusion set	Blood Transfusion (Administration) Set with vented	IIa

	Single drip chamber Blood Transfusion (Administration) Set with vented double drip chamber Blood Transfusion (Administration) Set with without Air vent Single drip chamber Blood Transfusion (Administration) Set with non-vented double drip chamber	
Mucus extractor with/without bacterial barrier filter	Adult, Child Mucus Extractor with Thumb Control (6FG, 8FG, 10FG, 12FG, 14FG): 25 ml, 40 ml, 100ml, 175ml	IIa
Nelaton catheter	6FG, 8FG, 10FG, 12FG, 14FG, 16FG, 18FG, 20FG, 22FG, 24FG	IIa
Stomach tube	Stomach tube with closed distal end (Size: 8FG, 10FG, 12FG, 14FG, 16FG, 18FG, 20FG, 22FG, 24FG) Stomach tube with open distal end (Size: 8FG, 10FG, 12FG, 14FG, 16FG, 18FG, 20FG, 22FG, 24FG)	IIa
Ryles tube	Ryles tube with luer connector: 6FG, 8FG, 10FG, 12FG, 14FG, 16FG, 18FG, 20FG, 22FG, 24FG (Tube length: 105cm) Ryles tube with luer connector: 18FG (Tube length: 80cm)	IIa
Suction catheter	With / without thumb control, finger-tip control, Connector, Graduation marking, single & double hole, Suction catheter (with hard thumb control open) Size: 5FG, 6FG, 8FG, 10FG, 12FG ,14FG, 16FG, 18FG, 20FG, 22FG, 24FG	IIa
Nebulizer mask	Adult & paediatric (child) , Mask with Dom shaped top cap Adult & paediatric (child)	IIa
Venturi mask	Adult & pediatrics (child)	IIa
High pressure vacuum drainage bottle with and without trocar	High Pressure Vacuum Drainage Bottle with extension tube: Small with 200ml, Medium with 400ml, Large with 600ml. High Pressure Vacuum, Drainage Bottle With Redon Tube & Trocar Needle: Small with 200ml, Medium with 400ml, Large with 600ml.	IIa
Tracheal tube	Endotracheal tube (Cuffed): 3.5mm, 4.0mm, 4.5mm, 5.0mmm, 5.5mm, 6.0mm, 6.5mm, 7.0mm, 7.5mm, 8.0mm, 8.5mm, 9.0mm, 9.5mm 10.0mm Endotracheal tube (Plain): 2.0mm, 2.5mm, 3.0mm, 3.5mm, 4.0mm, 4.5mm, 5.0mmm, 5.5mm	IIa
Feeding bag	1200 ml	IIa
Extension tube	High Pressure Extension Line: 20cm, 25cm, 35cm, 50cm, 100 cm, 150 cm, 200 cm, 300 cm. PE High Pressure Extension Line (Straight): 25cm, 50cm, 100 cm, 150cm, 200cm, 300cm, 400cm PE High Pressure Extension Line (Coiled): 25cm, 50cm, 100cm, 150cm, 200cm, 300cm, 400cm, Low Pressure Extension Line: 10 cm, 25 cm, 35	IIa

	cm, 45cm, 50 cm, 80 cm, 100 cm, 150 cm, 180 cm, 200 cm, 300cm Low Pressure Extension Line with clamp and latex Y port: 10 cm, 25 cm, 50 cm100 cm, 150 cm, 200 cm. Extension Tube Large bore Duo: 20 cm with ICU Needle free connector (Clear)	
Levins Tube	6FG, 8FG, 10FG, 12FG, 14FG, 16FG, 18FG, 20FG, 22FG, 24FG	IIa
Redon drainage tubes	Redon Drain Tube: 50cm, 70cm, 120cm. (6 FG, 8FG, 10FG, 12FG, 14FG, 16FG, 18FG)	IIa
Scalp vein set (winged infusion) with and without safety feature	Scalp vein (Winged Infusion) Set (with / without safety features 18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G	IIa
Oxygen catheter	6FG, 8FG, 10FG, 12FG, 14FG, 16FG, 18FG	IIa
Guedel Airways	Guedel Airway 000, Guedel Airway 00, Guedel Airway 0 Guedel Airway 1, Guedel Airway 2, Guedel Airway 3 Guedel Airway 4	IIa
Accessories of breathing circuit	Bain Circuit: Adult, Bain Circuit: Paediatric, Ventilator Circuit: Plain Adult, Ventilator Circuit: Adult with 1 water trap, Ventilator Circuit: Adult with 2 water trap, Ventilator Circuit: Paediatric, Ventilator Circuit: Neonatal, Ventilator Circuit: Neonatal with 2 water trap, HME filter	IIa
Under water sealed drainage system	Bag and bottle (Adult, Midi & Kid)	IIa
Peritoneal dialysis transfusion set	--	IIa
Rectal catheter	18FG, 20FG, 22FG, 24FG, 26FG, 27FG, 28FG, 30FG, 32FG, 34FG, 36FG,	Is
TUR set	--	Is

The complete list of devices is filed with the Notified Body

Certificate no.: C546185

Place and date: Høvik, 24 May 2024

Sites covered by this certificate

Site Name	Address
Vitromed Healthcare	A-22 to A-27, Bais Godam Industrial Estate, Jaipur, Rajasthan (India)-302006. Design, production and final product inspection/testing
Vitromed Healthcare	E 971- 972, G 973 – 974, Biotech Park, Sitapura Industrial Area, Jaipur, Rajasthan – 302022, INDIA For production, and final product inspection/testing

EU Representative
Obelis S.A., Boulevard General Wahis 53, 1030, Brussels, Belgium.

SAFEGUARDING LIFE, PROPERTY AND THE ENVIRONMENT
DNV
1864

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform the Notified Body of any intended updating of the quality system and the Notified Body will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. Notified Body reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.
- For the class III devices covered this certificate is dependent on the continued validity of the EU Technical Documentation Assessment Certificate, covering the devices.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window

Specific conditions - Class I devices, Systems and Procedure Packs:

- For class I device being placed on the market in a sterile condition, Class I devices with a measurement function and class I devices being reusable surgical instruments covered by this certificate the audit by the notified body of the quality management system was limited to the aspects required under article 52(7) of the regulation.
- For system and procedure packs being placed on the market in a sterile condition, covered by this certificate the audit by the notified body of the quality management system was limited to the aspects required under article 22(3) of the regulation.
- For Custom Made Class III implantable device the certification only relates to the Quality management system. Technical documentation assessment and issuance of EU Technical Documentation Assessment Certificate does not apply.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EU declaration of conformity and legally affix the CE mark followed by the Notified Body identification number.