

EC CERTIFICATE

Full Quality Assurance System

Certificate No.:
10000320741-PA-NA-IND Rev 3.0

Project No.:
PRJC-93692-2008-PRC-IND

Valid Until:
27 May 2024

This is to certify that the quality system of:

Vitromed Healthcare

A27/B-64, Polycon House, Bais Godam Industrial Estate, Jaipur, Rajasthan - 302006, India.

For design, production and final product inspection/testing of:
Sterile Disposable Medical Devices

Has been assessed with respect to:

**THE CONFORMITY ASSESSMENT PROCEDURE DESCRIBED IN
ANNEX II EXCLUDING SECTION 4 OF COUNCIL DIRECTIVE
93/42/EEC ON MEDICAL DEVICES, AS AMENDED**

and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

Place and date:
Høvik, 20 January 2020

For:
DNV GL PRESAFE AS
Notified Body No.: 2460

Eugenie Winger Husebye

The certificate is digitally verified by blockchain technology. For more info, see www.dnvgl.com/assurance/certificates-in-the-blockchain.html



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Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as "Forskrift om Medisinsk Utstyr" by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
0.0	Original Certificate	2019-10-24
1.0	Scope extension	2019-11-18
2.0	Editorial Change	2019-12-13
3.0	Editorial Change	2021-01-20

Products covered by this Certificate:

Product Description	Product Name	Class
<u>Infusion:</u>		
Intravenous cannula with / without safety feature	With/without wings & port, with Integrated Three way Stop cock, with tubing 14G, 16G, 17G, 18G, 20G, 22G, 24G, 26G, 27G	Ila
Stop cock (with and without extension tubing)	Multiway with/without lipid resistant, 45°click	Ila
Infusion Sets	Vented/Non Vented, with/without Flow Regulator, 3 Way Stop Cock, Micro Drip, 0.2micron inline Filter, Double Chamber and Needle Free Y Set, Auto stop function & Photo Fusion	Ila
Measured volume fluid administration set	Burette Set- 100ml, 110 ml, 150ml	Ila
Flow regulators	5ml to 250ml	Ila
Extension Tubes	Low or High Pressure, Coiled and PVC Free with and without needle free connector, Braided 10, 25, 50, 100, 150, 200, 250, 300, 400cm	Ila
Connection tube / Blood line set	Various lengths	Ila
Stylet. (Obturator)	14G, 16G, 17G, 18G, 20G, 22G	Ila
CVP Manometer	--	Ila

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Product Description	Product Name	Class
Scalp Vein (winged Infusion) set	With / without safety features 18G to 27G	Ila
<u>Blood Management:</u>		
Blood Transfusion set	With/without air vent	Ila
<u>General Surgery:</u>		
High Pressure vacuum drainage bottle	200, 400, 600ml, 1000 ml	Ila
Closed wound suction unit	50 ml, 200 ml, 400 ml, 600 ml and 800 ml	Ila
Yankaur suction set (suction tube and handle)	With and without Crown and standard tip	Ila
Thoracic Drainage Catheter with / without trocar and right angle	Size: 8FG - 42FG	Ila
Abdominal Drainage Set	20FG - 36 FG	Ila
Redon Drainage tubes	With and without trocar needle 8 FG - 18 FG	Ila
Under water sealed Drainage system	Bag and Bottle (Adult, Midi & Kid)	Ila
<u>Gynaecology:</u>		
Umbilical cord clamp	--	Is
<u>Urology:</u>		
Urine Bag	100 ml, 800ml – 2000ml Urine Collection Bag with top outlet, Urine Collection Bag with top outlet & Rod for hanging, Urine Collection Bag with bottom outlet, Urine Collection Bag with T- type bottom outlet, Urine Collection Leg Bag with bottom outlet, Pediatric Urine Collection Bag	Is
Urine collection bag with measure volume meter	With 250ml & 500ml Volume Meter and 2000ml urine collection bag	Is
Rectal Catheter	18 FG - 32FG	Is

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Product Description	Product Name	Class
TUR Set	--	Is
Female catheter	6 FG - 20 FG	Ila
Nelaton catheter	6FG - 24FG	Ila
Foley balloon catheter	Two Way & Three Way (Latex & Silicon)	Ila
<u>Gastroenterology:</u>		
Levins tube	5FG - 24 FG	Ila
Infant feeding tube	4 FG - 10 FG	Ila
Ryles tube	With and without connector 5FG - 24 FG	Ila
Stomach tube	8 FG - 24 FG	Ila
Mucus extractor with / without bacterial barrier filter	Adult, Child (6FG to 14FG) 25 ml, 40 ml, 100ml, 175ml	Ila
Feeding Bag	--	Ila
<u>Anaesthesia:</u>		
Suction Catheter	With / without thumb control, finger-tip control, Connector, Graduation marking Size: 5FG - 24FG	Ila
Nasal oxygen cannula	Adult, Paediatric, Neonatal	Ila
Oxygen catheter	6FG - 16FG	Ila
Guedel Airways	000, 00, 0, 1, 2, 3, 4, 5	Ila
Oxygen mask	Adult & paediatric (child)	Ila
Nebulizer mask	Adult & paediatric (child)	Ila
Venturi mask	Adult & paediatric (child)	Ila
Tracheal Tube	With / without cuff	Ila
Catheter Mount	--	Ila
Accessories of Breathing Circuits	Bain circuit, Ventilator circuit, HME filter	Ila
Laryngeal Mask Airway	Sizes: 0 – 5	Ila

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Product Description	Product Name	Class
Dialysis:		
Fistula needle with / without safety feature	Sizes: 15 G, 16 G & 17 G	Ila
Peritoneal dialysis catheter kit	Adult, child	Ila
Peritoneal Dialysis Transfusion Set	--	Ila

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	Address
Site I	A27/B-64, Polycon House, Bais Godam Industrial Estate, Jaipur, Rajasthan - 302006, India.
Site II	E-971-972 & G-973-974, Biotech Park, Sitapura Industrial Area, Jaipur, Rajasthan - 302 022, India.

EU Representative

Obelis s.a., Boulevard General Wahis 53, 1030, Brussels, Belgium.

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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 Presafe of any intended updating of the quality system and Presafe 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. Presafe reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

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

Conformity declaration and marking of product

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

End of Certificate