EC Certificate
Full Quality Assurance System

Certificate No.:
10926-2017-CE-IND-NA-PS

Project No.:
PRJC-04098-2007-PRC-IND

Valid Until:
12 September 2023

This is to certify that the quality system of:

Bio-Med Healthcare Products Pvt. Ltd.
Plot No. 62-65, Sector 6A, SIDCUL,
Haridwar – 249 403, Uttarakhand,
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, 12 September 2018

NORWEGIAN ACCREDITATION
PROD 021
Notified Body No.: 2460

For:
DNV GL PRESAFE AS

Palani Damodharan

The Certificate has been digitally signed.
See www.presafe.com/digital_signatures for more info

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

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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
	Original certificate	2018-09-12

Products covered by this Certificate:

Product Description	Product Name	Class
Infusion:		
Intravascular Catheters (I.V.Cannula)	I.V. cannula with wings & injection port. I.V. cannula with wings & without injection port. I.V. cannula without wings & without injection port. I.V. cannula without wings & without injection port (Pen Type) I.V. cannula with small wings & without injection port. I.V. cannula with suturable wings & snap fit port. SIZES: 14G, 16G, 17G, 18G, 20G, 22G, 24G, 26G Brand Name: Bio-Med, Bio-Flon, Bio-On, Bio-Can, Bio-Neo, Neo-Kath, Bio-Pen, Maxima	IIa
Sterile Hypodermic Single Use Syringe with or without Needles	Size: 1ml, 2ml, 3ml, 5ml, 10ml, 20ml, 50ml Brand Name: Bio-Med, Mr. Inject, Procare	IIa
Sterile Hypodermic Single Use Needles	Size: 16G, 17G, 18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G, 28G, 29G, 30G, 31G, 32G, 33G Brand Name: Bio-Med, Mr. Inject, Procare	IIa
Sterile Hypodermic Single Use Insulin Syringes	Size: 40 Units & 100 Units Brand Name: Bio-Med, Mr. Inject, Procare	IIa
Blood Administration Set	Blood Transfusion/ Giving Set Vented / Non-Vented Brand Name: Bio-Med	IIa

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Infusion Set (I.V. Set)	With or Without Air vent, Micro I.V. Set, with flow regulator, 3-way stop cock Measure Volume Administration Set (Paediatric / Burette Set – 100 ML, 110 ML, 150 ML) Brand Name: Bio-Med, Mr. Inject	IIa
Sterile single use Insulin Pen Needle	Size: 29G, 30G, 31G, & 32G Brand Name: Bio-Med	IIa
Anaesthesia:		
Endotracheal Tube	With / Without cuffed, Re-inforced Endotracheal Tube with / without cuffed Brand Name: Bio-Med	IIa
Urology:		
Urine Collection Bag	Urine Collection Bag (Adult / Paediatric), Urine leg bag Brand Name: Bio-Med	Is

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	Address
Bio-Med Healthcare Products Pvt. Ltd.	Plot No. 62-65, Sector 6A, SIDCUL, Haridwar – 249 403, Uttarakhand, India

EU Representative

Holden Medical B.V, Larserpoortweg 26, 8218 NK Lelystad, The Netherland

Phone: + 31 (0) 320296969, email: zee@imres.in

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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