

EC CERTIFICATE

Full Quality Assurance System

Certificate No.:
245989-2017-CE-IND-NA-PS Rev 1.0

Project No.:
PRJC-514010-2014-MSL- IND

Valid Until:
27 May 2024

This is to certify that the quality system of:

BIO-MED HEALTHCARE PRODUCTS PVT.LTD.
49/4, Mathura Road, Prithla, Palwal -121 102, Haryana, 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, 9 July 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	Supersedes DNVGL (NB 0434) Certificate no: 171809-2015-CE-IND-NA 2.0 following transfer to notified body functions to DNV GL Nemko Presafe AS (NB 2460)	2017-10-12
1.0	Recertification	2020-07-09

Products covered by this Certificate:

Product Description	Product Name	Class
Infusion:		
IV Cannula/Catheter With or Without Safety Feature)	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. I.V. Cannula with 3-way stop cock Brands: - BIO-MED BIO-FLON, BIO-ON, BIO-CAN, BIO-LEBON, BIOSIS, BIO CATH, BIO-NEO, NEO KATH. BIO-PEN,MAXIMA, BEX, INDOPLAS, INDOFLON, JRZ, I- INSTA, I-CURE, HARMED, BARAFLO, SOLIDOR, NOVA-FLON, PLUSMED, PLASMED, EASY CATH,EASY CATH PLUS, MEDICANN, ACCURE, TRIMED BIO FLON, AMBI-FLON, AMBI-ON, AMBI-CAN,AMBIKATH, AMBI-PEN, KKAREMAX, FARMABAN,MR.INJECT, OPTIMA,MEDICARE, INFUSAFE,MEDFLOW, REBONEL,COMCASET, MEDI-LIFE. Size :14G,16G,17G,18G,20G, 22G, 24G & 26G	IIa

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Three Way Stop Cock with or without Extension Tube	Three way stop cock with or without Extension Tube Lipid or Non-Lipid Resistant with Red, Blue, Yellow or White Handle and with or without pegs. Brands:- BIO-MED, SAFE-WAYS, NOVAFLEX, ALFA,SOLIDOR, PLUSMED, PLASMED, TRIMED SAFE-WAYS, LATEX,ACCURE , MAXIMA, INDOFLON, INDOPLAS, FARMABAN, BEX, MEDICANN, BIOSIS, JRZ,HARMED, MR.INJECT, OPTIMA, MEDICARE,INFUSAFE, MEDFLOW, REBONEL, IINSTA, I-CURE MEDI-LIFE. Size: - 5 cm to 500cm	IIa
Extension Tube / Pressure Monitoring Line	Low Pressure Extension Tube- 1 Way, 2 Way, 3 Way, 4 Way, T – Connector with or without clamp High Pressure extension tube Extension Set with Precision Flow Controller (Dial Type) Brands: - BIO-MED, ACCURE, ALFA, MAXIMA, FARMABAN, MR.INJECT, OPTIMA, MEDICARE, INFUSAFE, MEDFLOW, REBONEL,I-INSTA, I-CURE MEDI-LIFE. Size: - 5 cm to 500cm	IIa
Injection Stopper (Heparin Cap)	Brands: - BIO-MED, MAXIMA, ACCURE, MR.INJECT, OPTIMA, MEDICARE,INFUSAFE, MEDFLOW, REBONEL, I-INSTA,I-CURE MEDI-LIFE.	IIa
Flow Regulator	Flow regulator with extension line Brands :- BIO-MED, MAXIMA, ACCURE, MR.INJECT, OPTIMA, MEDICARE,INFUSAFE, MEDFLOW, REBONEL, I-INSTA,I-CURE , MEDI-LIF	IIa
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 (Pediatric / Burette Set- 100 ML, 110 ML, 150 ML) Brands :- BIO-MED, MAXIMA, ACCURE, MR.INJECT, OPTIMA, MEDICARE,INFUSAFE, MEDFLOW, REBONEL, I-INSTA,I-CURE, MEDI-LIFE.	IIa

The complete list of devices is filed with the Notified Body

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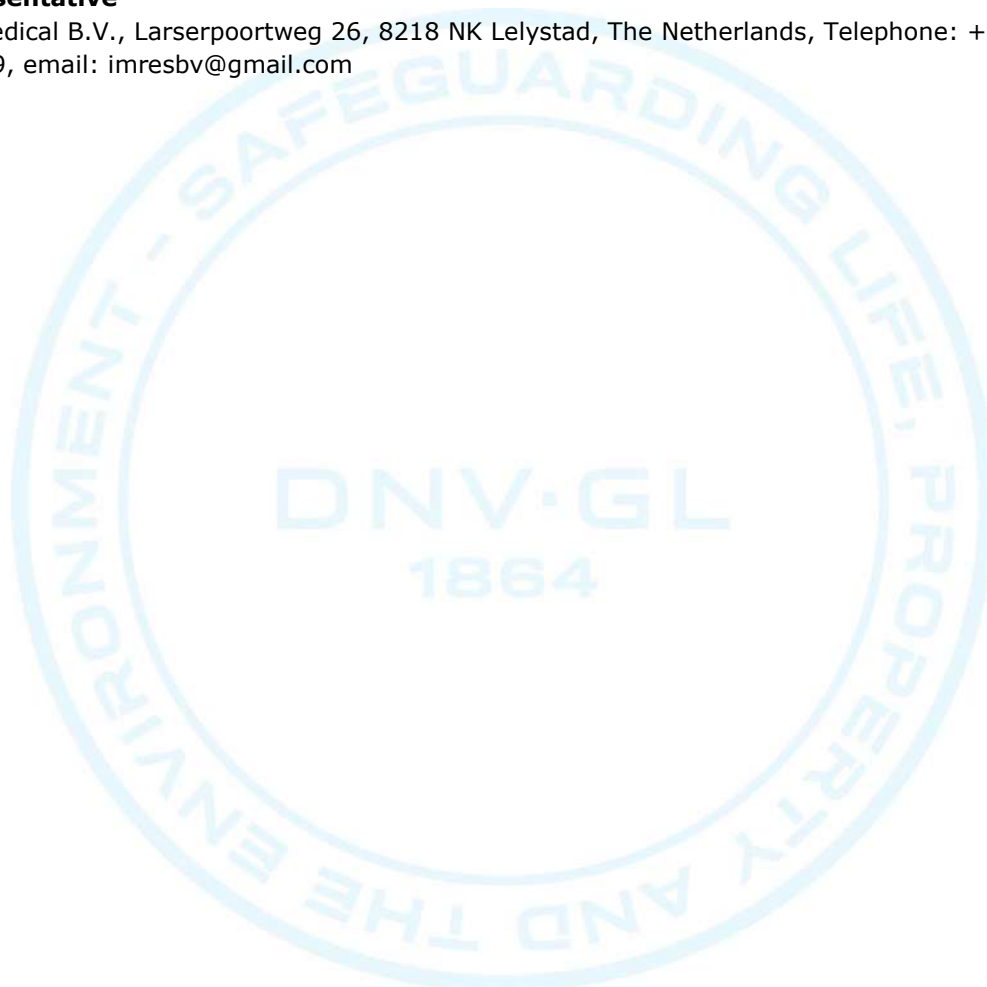
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Sites covered by this certificate

Site Name	Address
BIO-MED HEALTHCARE PRODUCTS PVT. LTD.	49/4, Mathura Road, Prithla, Palwal -121 102, Haryana, India.

EU Representative

Holden Medical B.V., Larserpoortweg 26, 8218 NK Lelystad, The Netherlands, Telephone: +31 (0) 320296969, email: imresbv@gmail.com



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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