EC CERTIFICATE

Full Quality Assurance System

Certificate No:10926-2017-CE-IND-NA-PS Rev 1.0 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, 26 March 2021

For the issuing office:
Notified Body 2460
DNV Product Assurance AS

Mariann Jeremiassen
Principal Assessor

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	2018-09-12
1.0	**Change in EC Rep and Deletion of Devices**	**2021-03-26**

Products covered by this Certificate:

Product Description	Product Name	Class
Infusion		
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
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
Anaesthesia:		
Endotracheal Tube	With / Without cuffed, Re-inforced Endotracheal Tube with / without cuffed Brand Name: Bio-Med	IIa

The complete list of devices is filed with the Notified Body

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Place and date: Høvik, 26 March 2021

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

M/s CMC Medical Devices & Drugs S.L. C/ Horacio Lengo N18, CP 29006, Málaga-Spain
Telephone: +34951214054
email: info@cmcmedicaldevices.com

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. the Notified Body 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.

End of Certificate