



# EC Certificate Full Quality Assurance System

Certificate No.:  
11186-2017-CE-IND-NA-PS Rev. 0.0

Project No.:  
PRJC-102278-2008-PRC-IND

Valid Until:  
24 August 2020

This is to certify that the quality system of:

## Poly Medicure Limited

Plot No. 104 - 105 UNIT I: Plot No. 104 – 105, Sector – 59,  
HSIDC Industrial Area, Ballabhgarh – 121 004, Faridabad, 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 Article 11.1.a  
and Annex II (Module H1) 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, 29 September 2017



For:  
DNV GL NEMKO PRESAFE AS

  
Alessandra Rinna

The Certificate has been digitally signed.  
See [www.presafe.com/digital\\_signatures](http://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
0.0	Supersedes DNVGL (NB 0434) Certificate no: 7045-2015-CE-IND-NA 0.0 following transfer to notified body functions to DNV GL Nemko Presafe AS (NB 2460)	2017-09-29

### Products covered by this Certificate:

Product Description	Product	Class
<b><u>Infusion:</u></b>		
IV Cannula with/without Safety Features	14G, 16G, 17G, 18G, 20G, 22G, 24G, 26G	IIa
IV Administration Set	Vented/Non Vented with/without Flow Regulator, 3 Way Stop Cock, Micro Drip, 0.2 micron Filter, Double Chamber and Needle Free Y Set, Auto Fusion & Photo Fusion	IIa
Polyvol Burette Set	100ml, 110ml, 150ml	IIa
Flow Regulators	5 -250 ml/hr	IIa
Extension Tubes (Multi lumen)	Low or High Pressure Coiled and PVC Free with and without needle free connector , Braided	IIa
Luer Locks		IIa
Stylet (Obturator)	14G, 16G, 17G, 18G, 20G, 22G	IIa
CVP Manometer		IIa
Stop cocks (with and without extension tubing)	2 way, 3 way, 4 way (Non Lipid / Lipid Resistant /click)	IIa
Needleless Swabable Access Site		IIa
Scalp vein (Winged Infusion) Set (with / without safety features)	18 to 27 G	IIa
Connection Tube		IIa
Insulin Syringes	U 40, U 100	IIa
<b><u>Transfusion:</u></b>		
Transfusion Pump Set		IIa

