



DET NORSKE VERITAS

EC CERTIFICATE - FULL QUALITY ASSURANCE SYSTEM

Certificate No. 85238-2010-CE-IND-NA
This Certificate consists of 5 pages

This is to certify that the Quality Management System of

Poly Medicure Limited

UNIT II: Plot No. 115-116, HSIDC Industrial Area, Ballabhgarh-121004, 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 11.3.a and Annex II excluding section 4 (Module H) of Council Directive 93/42/EEC on Medical Devices, as amended, and found to comply

Further details are given overleaf

Place and date:

Høvik, 26 November 2010

This Certificate is valid until:

24 August 2015

For DET NORSKE VERITAS CERTIFICATION AS
NORWAY



Eugenie Winger Husebye
Certification Manager



Notified Body No.:
0434

Jenny Helen Nytnun
Technical Reviewer

This Certificate has been digitally signed. See www.dnv.com/digitalsignatures for more info

Notice: The certificate is subject to terms and conditions overleaf. Any significant changes in design or construction may render this certificate invalid.

If any person suffers loss or damage which is proved to have been caused by any negligent act or omission of Det Norske Veritas, then Det Norske Veritas shall pay compensation to such person for his proved direct loss or damage. However, the compensation shall not exceed an amount equal to ten times the fee charged for the service in question, provided that the maximum compensation shall never exceed USD 300.000. In this provision "Det Norske Veritas" shall mean the Foundation Det Norske Veritas as well as all its subsidiaries, directors, officers, employees, agents and any other acting on behalf of Det Norske Veritas.



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

Jurisdiction

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

Certificate history

Revision	Description	Issue Date
	Original certificate	2005-08-24
	Recertification	2010-08-24

Products covered by this Certificate

Product Description	Product	Class
<u>INFUSION:</u>		
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	IIa
Luer Adaptors	20G, 21G, 22G	IIa
Polyvol Burette Set	100ml, 110ml, 150ml	IIa
Flow Regulators		IIa
Extension Tubes	Low or High Pressure and PVC Free	IIa
Luer Locks		IIa
Styilet (Obturator)	14G, 16G, 17G, 18G, 20G, 22G	IIa
Huber Infusion Set	19G, 20G, 22G	IIa
CVP Manometer		IIa
Scalp Vein (winged Infusion) Set with / without Safety Features	18G, 20G, 22G, 23G, 24G, 26G, 27G	IIa
Femoral Catheters	Large, Medium, Small	IIa
Safety Syringe with/without Needles	2ml, 3ml, 5ml, 10ml	IIa
Over the Needle		IIa
<u>TRANSFUSION:</u>		
Blood Transfusion Set	Vented / Non Vented	IIa
Blood Collection Set with / without Safety	20G to 26G	IIa
Blood collection Systems with/without Safety	18G, 20G, 22G, 24G	IIa
Blood Taking Set		IIa
<u>GENERAL SURGERY:</u>		
High Pressure Vacuum Drainage Bottle	200ml, 400ml, 600ml	Is



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Closed Wound Suction Unit	Novovac & Polyvac in Size 200ml, 400ml, 600ml, 800ml	IIa
Yankaur Suction Set with/without Handle	210cm, 250cm, 30cm	IIa
Thoracic Drainage Catheter	Straight, Curved with/without Trocar	IIa
Abdominal Drainage Set	20FG to 36FG	IIa
Redon Drainage Tubes	6FG to 18FG	IIa
Water Sealed Drainage System	Poly Drain, Polyseal – Adult, Midi & Kid	IIa
Blood Collection Needles	20G, 21G, 22G, 23G	IIa
<u>GYNAECOLOGY:</u>		
Umbilical Cord Clamp		Is
<u>UROLOGY:</u>		
Urine Bag	800ml, 2000ml with/without Top & Bottom Outlet, with Top Outlet & Rod, With T-Type Bottom Outlet & Sampling Port, Leg Bag Set, Paediatric in Size 100ml	Is
Rectal Catheter	18FG to 32FG	Is
Poly Urimeter	With 250ml & 500ml Volume Meter and 2000ml Urine Collection Bag	Is
TUR Set		Is
Female Catheter	6FG to 20FG	IIa
Nelaton Catheter	6FG to 24FG	IIa
Foley Balloon Catheter	Two Way Adult in Size 12, 14, 16, 18, 20, 22, 24 FG with Balloon Capacity 30ml Two Way Paediatric in Size 8, 10 FG with Balloon Capacity 3ml – 5ml Three Way Adult in Size 16, 18, 20, 22, 24 FG with Balloon Capacity 30ml – 50ml	IIa
Irrigation Set	Single Spike / Double Spike	Is
<u>GASTROENTEROLOGY:</u>		
Levins Tube	6FG to 24FG	IIa
Infant Feeding Tube	4FG to 10 FG	IIa
Ryle's Tube	6FG to 24FG	IIa
Stomach Tube	8FG to 24FG	IIa
Umbilical Catheter	4FG to 8FG	IIa
Mucus Extractor with/without Bacterial Filter	Adult, Child	IIa
Feeding Bag		IIa
<u>ANAESTHESIA:</u>		
Suction Catheter	5FG to 24FG	IIa
Nasal Oxygen Catheter / Cannula	Adult, Paediatric, Neonatal	IIa
Oxygen Catheter	6FG to 16FG	IIa



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Guedel Airways	000, 00, 0, 1, 2, 3, 4, 5	IIa
Oxygen Mask Set	Adult, Paediatric	IIa
Nebulizer Mask Set	Adult, Paediatric	IIa
Venturi Mask Set	Adult, Paediatric	IIa
Tracheal Tube	Plain, Cuffed	IIa
Catheter Mount		IIa
Epidural Needles	16G to 25G	III *
Spinal Needles	16G to 30G	III *
<u>DIALYSIS:</u>		
Haemodialysis Catheter	Double Lumen, J-Type	IIa
Peritoneal Dialysis Administration Set		IIa
Fistula Needle	15G, 16G, 17G	IIa
Peritoneal Dialysis Catheter Kit		IIa
		IIa

* Design assessment is covered by a separate design examination certificate no 85238-2010-IND-NA-D

The complete list of devices is filed with the Notified Body.

Sites covered by this certificate

UNIT II: Plot No. 115-116, HSIDC Industrial Area, Ballabhgarh-121004, Faridabad, India

EU Representative

M/s OBELIS, Avenue de Tervuerren, 34 bte 44, B-1040, Brussel, 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 the local DNV Office of any intended updating of the quality system and DNV 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 DNV 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 DNV.

END OF CERTIFICATE