



---

# DNV BUSINESS ASSURANCE

---

## EC CERTIFICATE - FULL QUALITY ASSURANCE SYSTEM

---

Certificate No. 89776-2010-CE-IND-NA rev 2.0

This Certificate consists of 5 pages

*This is to certify that the Quality Management System of*

### **Angiplast Private Limited**

Plot No - 4803, Phase - IV, GIDC Estate, Vatva, Ahmedabad, Gujarat, India 382445

*for design, production and final product inspection/testing of*

### **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, 25 November 2015

*This Certificate is valid until:*

**10 November 2020**

For DNV GL BUSINESS ASSURANCE  
NORWAY AS



---

Mariann Jeremiassen  
*Certification Manager*

Notified Body No.:  
0434

Aud Løken Eiklid  
*Technical Reviewer*

*This Certificate has been digitally signed. See [www.dnv.com/digitalsignatures](http://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.



Cert. No.: 89776-2010-CE-IND-NA  
 Rev. No.: 2.0  
 Project No.: PRJC-58690-2008-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 certificates 2005-OSL-MDD-0384 and 2005-OSL-MDD-0385	2005-11-10
	Recertification	2010-11-10
1.0	Models of Enteral Feeding Set included in the certificate (in bold)	2013-10-29
<b>2.0</b>	<b>Recertification</b>	<b>2015-11-10</b>

## Products covered by this Certificate

Product	Product Description	Class
Solution Administration Set (Infusion Set)	Infusion Set Vented / Non Vented (Economic/Standard Infusion Set), PVC /DEHP Free Infusion Set, Needle free infusion set, Infusion Set for Taxol (Paclitaxel) Administration, Filter Administration Set, Infusion Set for Infusion Pump, Infusion Set for Photosensitive (light proof) Drugs, Pediatric Infusion Set, Secondary Medication I.V. Set, Infusion Set with Precision Flow Controller (Dial Type), Scalp vein set (Winged Infusion Set) . Measured Volume Solution Administration Set (Burette Set - 100/110/150 ml), Solution Administration Set with Scalp Vein Set. Infusion Set for veterinary Use.	IIa
Blood Administration Set	Blood Transfusion/ Giving Set Vented/Non Vented, Transfusion Burette Set.	IIa
Tubes & Catheters	Nelaton Catheter, Infant Feeding Tube, Suction Catheter, Levin's Tube, Thoracic Catheter (Chest Drainage Catheter), Ryle's Tube (Deodenal Ryle's Tube) , Umbilical Catheter, Rectal Catheter, Urethral Catheter, Stomach Tube, Infant Mucus Extractor (with/without filter)	IIa
Urine Collection Bag	Urine Collection Bag (Adult/ Pediatric) ,Urine leg bag,	Is
Umbilical Cord Clamp	Umbilical Cord Clamp Non-reopenable/Openable	Is
Corrugated Drainage Sheet	Corrugated Drainage Sheet	IIa
Karman Cannula	Karman Cannula with /without adaptor	IIa
Nasal Oxygen Catheter	Nasal Oxygen Catheter	IIa
Disposable Syringe	Disposable Syringe with/ w/o Needle -1 ml, 2ml, 3ml, 5ml, 10ml, 20ml, 50ml. & Insulin Syringe	IIa
Peritoneal Dialysis Set	Peritoneal Dialysis Set - Y type for two containers	IIa
T.U.R. Set	T.U.R. Set /Y Junction Set	IIa
Vaccum Suction Set	Vaccum Suction Set / Yankauer Suction Set (Plain/Bulb tip) and Suction tubing	IIa



Cert. No.: 89776-2010-CE-IND-NA  
 Rev. No.: 2.0  
 Project No.: PRJC-58690-2008-PRC-IND

Blood Donor Set	Blood Taking Set	IIa
Intravenous Cannula / Catheter	I.V. Cannula with injection port.& Wings I.V. Cannula with wings and without injection port. I.V. Cannula without injection port.& Wings	IIa
Wound Drainage System	Wound Suction Set (Adult / Pediatric) - 50,250,400,600,800 ml Redon Drain Catheter	IIa
Folly Balloon Catheter	Folly Balloon Catheter (Urological Catheter) – Two/Three way Latex- Silicon Coated / 100 % Silicon	IIa
Thoracic Catheter with Trocar	Thoracic / Chest Drainage Catheter with Trocar	IIa
Guedal Airway	Guedal Airway	IIa
Abdominal Drain Kit	Abdominal Drain Kit (ADK)	IIa
Extension Set / Pressure Monitoring Line	Extension line, Extension line with three way stop cock Pressure Monitoring Line. ( High/Low Pressure) Extension Set with Precision Flow Controller (Dial Type)	IIa
Three Way Stopcock	Three Way Stopcock	IIa
Disposable Needle	Disposable Needle with Protector (Different sizes)	IIa
Enteral Feeding Set- Pump Set	Enteral Feeding Set / Feeding Bag with Set	IIa
Enteral Feeding Set - Gravity Transfer Set	Enteral Feeding Set / Feeding Bag with Set as well as Fluid Bag	Is
Water Sealed Drainage System	Water Sealed Drainage System (Chest Drainage System)	Is
Male Incontinence Device	Male External Catheter (Condom Catheter)	Is
Nasal Oxygen Cannula	Nasal Oxygen Cannula,Twin bore Set (Adult/Paediatric/Infant)	Is
Oxygen Mask	Oxygen Mask (Adult/Paediatric/ Infant)	Is
Colostomy Bag	Colostomy Bag one System./ two system, (Ostomy Bag, Colostomy Pouch )	Is
Urostomy Bag	Urostomy Bag (one & two system)	Is
Endotracheal Tube	Endotracheal Tube with / w/o cuffed, Re-inforced Endotracheal Tube with / w/o cuffed	IIa
Tracheostomy Tube	Tracheostomy Tube with / w/o cuffed	IIa
Urine meter with Drainage Bag	Urine meter with Drainage Bag -200,250,350,400,500 ml	Is
Kher's 'T' Tube	Kher's 'T' Tube	IIa
Venturi Oxygen Mask	Venturi Oxygen Mask (Adult/Paedriatic)	Is
Nebulizer Mask	Nebulizer Mask (Adult/Pediatric/ Infant)	Is
CVP Manometer	CVP Manometer with Extension Set	IIa
Dialysis Blood Line	Blood Tubing for Hemodialysis (Post-Pump / Pre-Pump Arterial & Venous Line )	IIa
Surgical Gloves	Surgical Gloves Pre-powdered / Powder Free (Rubber Latex)	IIa
Cannula Fixator	Cannula Fixator (PU/ non Woven)	Is
Injection Stopper	Female Luer Lock Cap	Is



Cert. No.: 89776-2010-CE-IND-NA  
 Rev. No.: 2.0  
 Project No.: PRJ-58690-2008-PRC-IND

AV Fistula Needle	AV Fistula Needle Size: 15 G, 16 G , 17 G	IIa
Bain Circuit	Adult/ Child	IIa
Safety Cannula/Catheter	Safety IV Cannula with injection port and wings. Safety IV Cannula with injection port and without wings. Safety IV Cannula without injection port & wings.	IIa
Double Swivel Mount	Catheter T Mount	Is
Breathing System	Breathing System With Single/ Double Water Trap	IIa
Heat And Moisture Exchange Filter	HME Filter	Is
Ventilator Circuit	Ventilator Circuit (corrugated/ Expandable pipe)	IIa
Peritoneal dialysis catheter kit	Adult/ Child	IIa
Gas Line Filter - 0.2 Micron	Gas Line Filter - 0.2 Micron	Is
Nephrostomy Set	Percutaneous Pigtail Nephrostomy Catheter Set Sizes: 6, 7, 8, 9, 10, 12, 14, 16 FG	IIa
Urethral Stent Set	Urethral Indwelling Double Pigtail Stent Set Size: 3 F to 26 F.	IIa
Anaesthesia Face Mask	Size: 0 , 1 , 2 , 3 , 4 , 5	Is
Silicon Wound Drainage System	Silicon Wound Drainage System Sizes: 100 ml, 200 ml, 400 ml, 600 ml, 800 ml	IIa
Nasopharyngeal Air Way	Nasopharyngeal Air Way [ Size: 2.5 , 3.0 , 3.5 , 4.0 , 4.5 , 5.0 , 5.5 , 6.0 , 6.5 , 7.0 , 7.5 , 8.0 , 8.5 , 9.0]	IIa
Laryngeal Mask Airway	Disposable / Reusable (Silicon) Sizes: 1.0 , 1.5 , 2.0 , 2.5 , 3.0 , 4.0 & 5.0.	IIa
Drain Bag	Drain Bag Empty System (CAPD fluid drain bag set)	Is
Fourie Safety System	With & Without Agitator Bulb	Is

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

#### Sites covered by this certificate

Site Name	Address
Angiplast Private Limited	Plot No - 4803, Phase - IV, GIDC Estate, Vatva, Ahmedabad, Gujarat State, India 382445

#### EU Representative

Name	Address
mdi Europa GmbH	Langenhagener Str 71, 30855, Langenhagen, Germany



Cert. No.: 89776-2010-CE-IND-NA  
Rev. No.: 2.0  
Project No.: PRJ-58690-2008-PRC-IND

## 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