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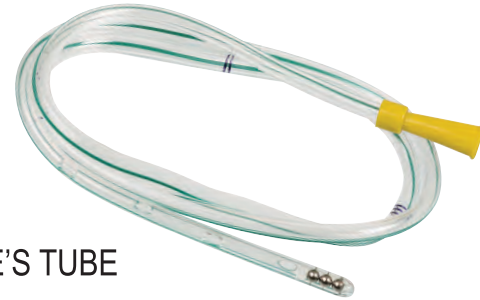


PRODUCT CATALOGUE

GASTROENTROLOGY / UROLOGY



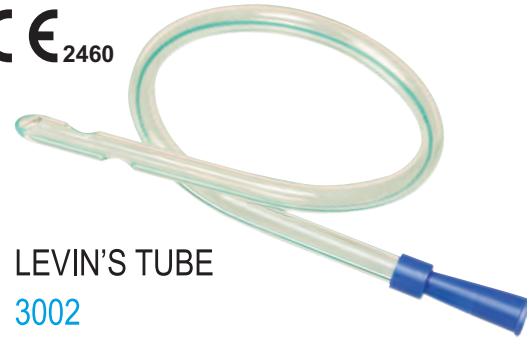
CE 2460



RYLE'S TUBE
3001

- 105cm long PVC Tube made from non toxic PVC Compound.
- Marked at 3 locations for indicating catheter position.
- Radio opaque line along the length of tube for radiological determination of the location of tube.
- Distal end with four Lateral eyes at 90° Orientation.
- Tip weighted with three round stainless steel balls in the closed round distal end for smooth intubation.
- Colour coded Funnel shaped connector with standard 60° taper for fitment with any standard male device.
- Size ranging from FG 8 to FG 22. Tube length can be changed as per customer option.

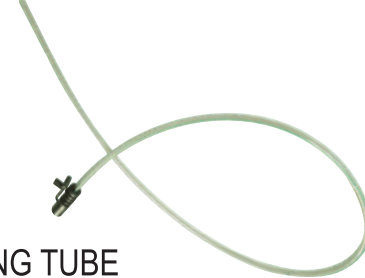
CE 2460



LEVIN'S TUBE
3002

- 125cm long PVC Tube made from non toxic PVC Compound.
- Marked at 4 locations for indicating catheter position.
- Radio Opaque line along the length of tube for radiological determination of the location of tube.
- Closed Distal end with four Lateral eyes at 90° Orientation.
- Colour coded Funnel shaped connector with standard 6% taper for fitment with any standard male device.
- Size ranging from FG 8 to FG 24. Tube length can be changed as per customer option.

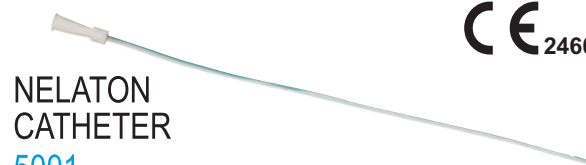
CE 2460



INFANT FEEDING TUBE
6001

- 60cm long PVC tube made from non toxic PVC compound.
- Marked at 20 cm's from distal end for indicating catheter position.
- Radio opaque line along the length of tube for radiological determination of the location of tube.
- Smooth Closed Distal end with two Lateral eyes at 180° Orientation.
- Colour coded Funnel shaped connector with standard 6% taper for fitment with any standard male device.
- Available in Size FG 4, 5, 6, 7, 8 and 10. Tube length can be changed as per customer option.

CE 2460



NELATON CATHETER
5001

- 40/18 cm long PVC Tube made from non toxic PVC compound
- Radio Opaque line along the length of tube for radiological determination of the location of tube.
- Closed Tip Distal end with 2 Lateral eyes at 180° Orientation.
- Coloured coded Funnel shaped connector with standard 6% taper for fitment with any urine bag with standard male connector.
- Size ranging from FG 8 to FG 22. Tube length can be changed as per customer requirement.

CE 2460



FOLEY BALLOON CATHETER
5003

- Used for short/long term urine drainage
- Symmetrical large capacity balloon ensuring a straight tip for proper flow and good Sphincter action thus preventing leakage
- Hard valve ensures easy inflation & deflation of balloon
- Colour coded for instant size identification
- Sterile, individually packed.
- Available in Two way and Three way variants.
- Available sizes-8FG to 26 FG

WELLMED - HOUSE OF CARE, PAR EXCELLENCE

Wellmed's state of art manufacturing facility caters to a capacity of 45 million units per annum. Equipped with semi and fully automated machinery, this facility adheres to strictest quality norms and strives for excellence in manufacturing,

Wellmed ensures high reliability of products through in-house processing of raw materials-compounding of PVC, tube extrusion & injection moulding using latest available microprocessor controlled machines, assembly in class 10,000 clean room, packaging in soft / hard blisters and SCADA controlled sterilization process validated under ISO 11135. A fully equipped in-house laboratory further facilitate quality monitoring.

One of the hallmark's of Wellmed's evolution as a major medical products supplier is the on going in-house research and development of proprietary equipment, tool design & development, manufacturing techniques and process management. This capability has enabled wellmed to emerge as an innovative manufacturer and to better satisfy customers and their challenging needs.



I.V.Cannula




WELLCATH *Plus*
1001

I.V.Cannula with Injection Port & Wings

- Injection Port with unidirectional valve for facilitating extra medication and preventing back flow.
- Specially engineered recessed plug with ring, to avoid risk of contamination
- Angled & grooved wings for easy cannulation and to prevent rolling of cannula over patient's body.
- Colour coded cap for easy identification of gauge size.
- Needle Hub designed for proper grip during insertion.
- Flash Back chamber allows easy visualization of blood, confirming correct placement of Catheter
- Optional Hydrophobic filter/Porous plug in Flash back chamber available on demand




WELLCATH *Alfa*
1002

I.V.Cannula with Wings, without Injection Port

- Angled & grooved wings for easy cannulation and to prevent rolling of cannula over patient's body.
- Colour coded body for easy identification of gauge size.
- Needle Hub designed for proper grip during insertion.
- Flash Back chamber allows easy visualization of blood, confirming correct placement of Catheter.
- Optional Hydrophobic filter/Porous plug in Flash back chamber available on demand




WELLCATH
1003

I.V.Cannula without Injection Port & without Wings

- Designed to ensure correct Orientation of needle bevel & better control during cannulation.
- Needle Cover designed for safe disposal of needle after Catheterization.
- Colour coded body for gauge size identification.
- Needle Hub designed for proper grip during insertion.
- Flash Back chamber allows easy visualization of blood, confirming correct placement of Catheter
- Optional Hydrophobic filter/Porous plug in Flash back chamber available on demand




INFANT MUCOUS EXTRACTOR
6002

- Transparent Burette of 20ml Capacity graduated to indicate volume of extract collected.
- Leak proof cap made of Medical Grade PVC for fitment on the burette fitted with a round chamfered tip Suction catheter for inter oral aspiration and a tube fitted with standard funnel connector with standard 6% taper for fitment with male fitment of 50ml Syringe or for suction through mouth.
- Supplied with a plain cap for disposal or transportation.
- Option of Catheter from FG 10 to FG 14 at customer's option.
- Device with filter supplied on customer's option.




UMBILICAL CORD CLAMP
6003

- Lock designed with care to avoid accidental opening.
- Teeth designed to firmly hold umbilical cord.
- Serrated Finger grip provided for firm grip even when used with wet gloved hands.
- Choice of Blue, White or Pink Colour.




PERFORATOR
6004

- Certain Grip design: provides a secure grip on insertion, rotation, and removal
- Flexible 254mm Long Handle: prevents injury to mother and fetus during insertion
- Safe Hook Geometry: allows for easy snagging motion instead of poking




A.V.FISTULA NEEDLE
5002

- Ultra thin siliconised Lancet Point Needle of Japanese origin with Back Eye.
- Butterfly shape wings Colour coded connector provided on the needle Hub for ease during application.
- 35cm long Frosted tube made of medical grade PVC Compound.
- Distal end of the tube fitted with Female Luer confirming to satandard ISO:80369-7:2016 for safe fitment.
- Size range 15G, 16G and 17G.

SURGERY & WOUND DRAINAGE PRODUCT



C L O S E W O U N D D R A I N A G E S E T



WELLSUC
7001 - 800

WELLSUC
7001 - 400

- 50/400/800 cc bellow designed for close wound drainage under pressure.
- 64 smooth hole non toxic medical grade PVC catheter for suction.
- Radio opaque line through entire length of catheter for radiological determination of location.
- Supplied with suitable size curved knife point stainless steel trocar.
- Option to use one or two catheters.



WELLSUC
7001 - 50

YANKAUR SUCTION SET 7004

- 2mts. long Non toxic medical grade PVC Tube provided with ribs for firm grip
- Standard or Crown Tip Yankur Handle available with or without Vacum Control.



CHEST DRAINAGE CATHETER WITH TROCAR

7003

- 45cm long frosted catheter made of non toxic, PVC compound.
- Radio opaque line through entire length of catheter for radiological determination of location.
- 2 Lateral eyes at a length of 7mm from distal end.
- 10 Markings at 2cm interval from the second eye.
- Trocar provided with T shaped Handle for firm grip.
- Three facet distal end of the Trocar provided with conical PVC tip connector for ease during intubation.
- Size Ranging from FG 08 to FG 40
- Optionally available in pthalate free version



THORACIC DRAINAGE CATHETER CURVED / STRAIGHT

7002 C / 7002 S

- 45cm Long frosted catheter made of non toxic, PVC compound.
- Smooth Chamfered distal end
- Radio opaque line through entire length of catheter for radiological determination of location.
- 6 Lateral Eyes with last at a distance of 90mm from diastal end
- 10 Markings at 2cm interval from the last/6th eye
- Size Ranging from FG 08 to FG 40°
- Optionally available in pthalate free version



REDON DRAIN 7001 - 011

- Kink Resistant, Soft frosted tube from medical grade PVC Compound
- Cross Perforated 8, 16, 32, or 64 smoth holes as per customer requirement.
- Markings on tube, 19cm from the distal end



TRANSFUSION & INFUSION



I.V.Cannula

CE 2460



WELLNEO
1004

**I.V.Cannula with Wings
for Neonates**

- Projection on main body & wings for easy cannulation and secure fixation.
- Needle Hub designed for proper grip during insertion.
- Flash Back chamber allows easy visualization of blood, confirming correct placement of Catheter.
- Optional Hydrophobic filter/Porous plug in Flash back chamber available on demand.
- Optional removable wing enclosure

CE 2460



PENCATH *Plus*
1005

**I.V.Cannula without Injection
Port & without Wings**

- Designed to ensure correct orientation of needle bevel & better control during Cannulation.
- Color coded body for easy identification of gauge size.
- Packed in pen shaped plastic moulded body for convenient handling and safe disposal of needle.
- Needle Hub designed for proper grip during insertion.
- Flash Back chamber allows easy visualization of blood, confirming correct placement of Catheter.
- Optional Hydrophobic filter/Porous plug in Flash back chamber available on demand.

CE 2460



PENCATH
1006

**I.V.Cannula without Injection
Port & without Wings**

- Designed to ensure correct orientation of needle bevel & better control during cannulation.
- Needle Cover designed for safe disposal of needle after catheterisation.
- Colour coded body for gauge size identification.
- Provided with porous plug for faster flash back
- Needle Hub designed for proper grip during insertion.
- Flash Back chamber allows easy visualization of blood, confirming correct placement of Catheter.
- Optional Hydrophobic filter/Porous plug in Flash back chamber available on demand.

I.V.Cannula



PÜRfect

I.V.Cannula range with Polyurethane as catheter material

- **PÜRfect** Plus (I.V.Cannula with Injection Port and Wings). Ref.: 1001 P
- **PÜRfect** X Plus (I.V.Cannula with Injection Port and Sutures Wings) Ref.: 1001XP
- **PÜRfect** *Alfa* (I.V.Cannula with Wings and Without Port). Ref.: 1002 P
- **PÜRfect** Cath (I.V.Cannula without Injection Port and without Wings) Ref.: 1003 P
- **Pencath PÜRfect** (I.V.Cannula without Injection Port and without Wings) Ref.: 1006 P
- **Neo PÜRfect** (I.V.Cannula with Wings for Neonates),Ref.: 1004P



WELLCATH
X Plus
1001 X
I.V. Cannula with Injection port & Sutures wings

- Ergonomically designed wings to facilitate longer usage
- Wings provided with holes for fixation of I.V. Cannula with suture on patient's body
- Colour coded body for ease of size identification
- Snap fit port cap
- Flip type Port cap also optionally available which increases patient comfort as the protective cap of Injection Port opens and closes almost effortlessly

TRANSWELL
TRANSFER SPIKE
2045



- Closed System Transfer Device for rapid transfer of medication / diluent between stoppered bottles / bags.

IV Cannula Specifications				
Size	Colour	Int./Ext. (ø in mm)	Length* (in mm)	Water Flow Rate (in mL./min)
14G	Orange	1.72/2.1	45	280
16G	Grey	1.3/1.8	45	200
17G	White	1.15/1.5	45	130
18G	Green	0.95/1.30	45	95
20G	Pink	0.75/1.1	32	61
22G	Blue	0.6/0.9	25	36
24G	Yellow	0.48/0.72	19	20
26G	Violet	0.44/0.6	19	13
* Shorter length available on demand				



GUEDAL AIRWAY
8007

- Milky coloured Air Way made from Non-toxic material
- Integral Hard Bite Block colour code for size identification
- Available in size: 000, 00, 0, 1, 2, 3, 4, 5



SUCTION
CATHETER

- Made from medical grade non toxic PVC compound.
- Round open distal end for avoiding injury to sub-mucosa tissue.
- Connector Options:
 - Plain
 - Finger Tip Control
 - Thumb Control
- Size: FG 6 to FG 24, 60cm long



TWIN BORE NASAL OXYGEN SET
OXYAID
8006

- Extra soft nasal prongs made of Medical Grade PVC Compound
- Choice of Flared, Curved or Pediatric Nasal Prongs
- Two channelizing tubes 50cm long provided on both side of nasal prongs with a sliding sleeve for securing placement to avoid unintentional displacement from the nostrils.
- Star Lumen Tube for avoiding un-interrupted Oxygen supply even if tube unintentionally gets folded in length as per customer's requirement.
- Distal end of the tube with 6% taper connector for snug fitment with any Oxygen supply source with standard outlet.



CE 2460

WELLMASK

8001

- Medical grade PVC odourless or Vanila scented soft and transparent mask
- Supplied with 1.5M longer star lumen Tube to ensure uninterrupted supply of Oxygen even if the tube gets folded for any reason.
- Provided with anodised aluminium clip for adjusting the mask according to the profile of the patient's face.
- Elastic strap for holding the mask in place.
- Available in smaller size for infants.



CE 2460

WELLNEB

Nebulizer kit with face mask

8002

- Medical grade PVC odourless or Vanila scented soft and transparent mask
- Supplied with 1.5M or longer star lumen Tube to ensure uninterrupted supply of Oxygen even if the tube gets folded for any reason.
- Provided with anodised aluminium clip for adjusting the mask according to the profile of the patient's face.
- Elastic strap for holding the mask in place.
- Designed for optimum nebulization.
- Graduated for proper medication.



CE 2460

WELLMASK NRB

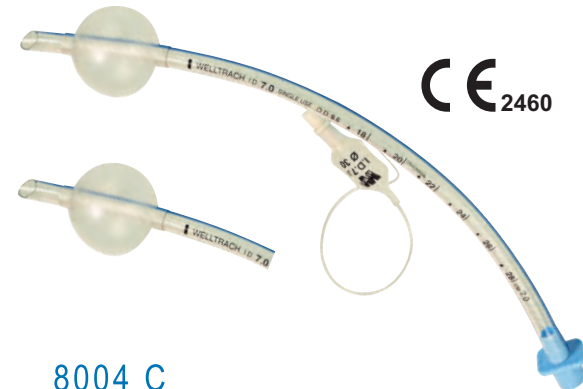
8003

- Medical Grade PVC odorless or Vanilla scented soft and transparent Mask.
- Supplied with 1.5M or long star lumen Tube to ensure uninterrupted supply of Oxygen even if the tube gets folded for any reason.
- Provided with anodized aluminium clip for adjusting the mask according to the profile of the patient's face
- Elastic strap for holding the mask in place.
- Available in smaller size for infants.

WELLTRACH ENDOTRACHEAL TUBE WITH / WITHOUT CUFF

- Sturdy medical Grade PVC tube designed to keep the respiratory tract of the patient open during general anesthesia.
- Provided with convenient distance and depth marks to indicate distance between the distal end and mouth/nose of the patient.
- Radio Opaque line provided for Radiological dertermination of position of tube.

- Smooth finish Murphy Eye and Smoth Beveled Distal end provided to ensure trauma free intubation.
- Available in size 2 to 11mm ID with standard OD in steps of 0.5mm
- Tube with cuff 100% leak tested.
- Non Return Valve in Pilot Balloon designed for quick release as well as for avoiding leakage from inflation line.



CE 2460

8004 C



CE 2460

8004

NEEDLE



- High Precision Stainless Steel Japanese Needle.
- Back Cut, Ground and Siliconized for low penetration force and smoth venipuncture.
- Choice of Two Point Bevel or Four Point Bevel Cannula

FOUR POINT BEVEL



- Sharpness of the point reduces vein puncture resistance.
- Vein Puncture Trauma is minimized due to lower wall thickness of the point.
- Pin Point Slant angle minimize chances of damaging inside wall of blood vessel and minimize chances of cutting off small piece of patient skin or blood vessel.

FEP / PUR / PTFE / ETFE Catheter



- Choice of FEP / PU / PTFE / ETFE,conforming to USP class VI for Biological reactivity
- Dual tapered and beveled tip.
- Siliconised for lower resistance during insertion & fold back prevention.
- Optimum trim distance.
- Optional stripped/radiopaque/transparent catheter.

I.V. Cannula with safety feature



CE 2460

- Designed to cover and protect needle from causing accidental needle prick injury
- Works on conventional vein puncture procedure

1003S-2

- Safety shield stays in place Through disposal.

1003S-3

WELLPORT

Accessport (HEPARIN CAP)

100U-11

- Designed for providing access to the catheter for injecting Heparin or drawing blood through the injection membrane, using syringe.
- Injection membrane tested as per ISO:8536-4 for self sealing. Optionally available with latex free injection membrane
- Luer conforming to ISO:80369-7:2016 for suiting the female end of any standard product.

CE 2460



WELLCAP

Luer Cap

100U

- Male Fitting Provided with standard 6% Taper to ensure proper fitment and for avoiding leakage of fluid from Female fitting of any make with standard dimensions.
- Thread confirming to ISO 80369-7:2016 for appropriate fitment with any standard device.

CE 2460





Infusion Set



WELLFUSION ALPHA
- Air Vented Infusion set

- Conforming to ISO:8536-4
- Rigid Plastic Spike engineered for smooth puncture & leak free operation.
- Air vent hole of spike for Air Vented Wellfusion Alpha fitted with Bacteria Filter.
- Highly transparent, soft drip chamber made from medical grade PVC compound for ease of monitoring drop rate and priming.
- Soft medical grade kink proof PVC tube.
- Flow regulating clamp specially engineered for smooth adjustment of flow rate as well as stable drop count.
- Male Luer as per ISO: 80369-7:2016 for snug fitment with standard female connector.
- Also available in DEHP (PTHALATE) free option



WELLFUSION
- Non Vented Infusion set

Product Code/Ref. No		Configuration	Drop Rate
Non-Vented		Air Vented	
2011	2021	Macro Drop, with Latex Bulb. Slip on Luer & 21G 1.5" Needle	20=1ml+/-0.1ml
2012	2022	Macro Drop, with Latex Bulb Luer Lock & 21G 1.5" Needle	20=1ml+/-0.1ml
2013	2023	Macro Drop, with "Y" type injection port. Slip on Luer & 21G 1.5" Needle	20=1ml+/-0.1ml
2014	2024	Macro Drop, with "Y" type injection port. Slip on Luer & 21G 1.5" Needle	20=1ml+/-0.1ml
2015	2025	Micro Drop, with Latex Bulb, Slip on Luer & 23G 1" Needle	60=1ml+/-0.1ml
2016	2026	Micro Drop, with Latex Bulb, Luer Lock & 23G 1" Needle	60=1ml+/-0.1ml
2017	2027	Micro Drop, with "Y" type injection port. Slip on Luer & 23G 1" Needle	60=1ml+/-0.1ml
2018	2028	Micro Drop, with "Y" type injection port. Luer Lock & 23G 1" Needle	60=1ml+/-0.1ml



WELLCALIB
2031
Micro Drop (60 Drops=+/-0.1ML) I.V. Set with a 150ML/100ML Cylindrical Burette for infusing a measured volume of I.V. Solution.

- Conforming to ISO:8536-5
- Flexible, transparent and graduated Burette with 5ml graduation.
- Rigid Plastic Spike for smooth puncture and leak free operation.
- Self sealing injection port in the Cap for adding extra medication in the Burette.
- Burette Cap fitted with Bacteria Barrier Filter in air vent.
- Floating auto shut off valve for automatic shutdown of the Burette drain path for avoiding air embolism.
- Male Luer conforming to ISO: 80369-7:2016 for snug fitment with any standard female connector.
- Highly transparent & soft drip chamber, made from medical grade PVC compound for ease of monitoring drop rate and priming.
- Constant flow rate regulating clamp specially engineered for smooth adjustment of desired flow rate as well as stable drop count.
- Soft medical grade kink proof PVC tube.
- Self Sealing Latex Bulb or "Y" type injection port for extra medication.



- D'SCIENCE
Three Way stop cock
9000 / 9000LR
- Designed to facilitate smooth switching of Infusion from multiple lines.
 - Conforms to ISO 8536-10
 - Rotating luer lock and threaded Female ports complying with ISO: 80369-7:2016 for safe and secure fitment with any other device.
 - We have both Lipid Resistant (9000LR) & Non Lipid Resistant (9000) 3Way stop Cock
 - Also available on demand 'EASY EJECT' feature.
 - High pressure variant available
 - Variant available with clicks every 45°



- WELLWAY EX
Three Way stop cock
with Extension Tubing
9000 EX / 9000LR EX
- Used for shifting manipulation site away from the venipuncture site.
 - Three Way Stop cock, facilitates administration of additional fluid from the side port as well as switching the lines.
 - Available in tube length ranging from 5 cm to 500 cm



Extension Tube
Wellex 2042

- Medical grade PVC tube for extending lines.
- Equipped with Male and Female Luer connector coforming to ISO: 80369-7:2016
- Available in 10, 25, 50, 100, 150, 200 cm length.

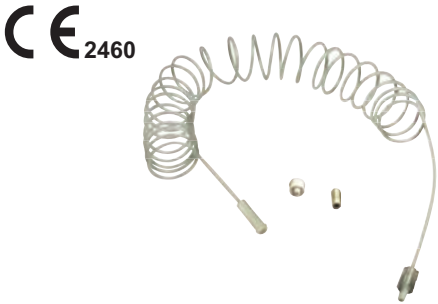
High Pressure Extension Tube

Wellex HP
2041

- Medical grade PVC tube for extending lines used at high pressure.
- Equipped with Male and Female Luer connectors conforming to ISO:80369-7:2016 Pressure tested at 40kg/cm2.
- Available in 10, 25, 50, 100, 150, 200cm length.
- Available with Red or Blue line for use as Arterial or Veinous line.



Wellex Coil
2043



Multiway Extension Tube



- 2044 : Double , 2044L : Double+luerlock , 2044(4W) : Quadruple , 2044(4WL) : Quadruple+luerlock
- Intended for disposable use for connection of one/two or multiple infusion lines.
 - Transparent PVC tube terminated with double or quadruple Female Luer Lock / Male Luer Lock.
 - Slide clamps provided to close a particular fluid path
 - All Luers are given universal 6% tapers as per ISO 80369-7
 - The PVC tube is Phthalate free

*Wellmed is Committed to serve the
mankind with highest reliability and fit for
Purpose medical devices. We firmly believe
that in healthcare, there can be no
Compromises. This Philosophy shapes our
mission and objectives.*

Customer Satisfaction is our mantra

Rajinder Malhotra
C.E.O.

Management System Certificate

Certificate No.:
247997-2017-AQ-IND-NA-PS Rev. 1.0

Project No.:
PRJC-166238-2009-MS-IND

Initial Certification Date:
24 OCTOBER 2017

Valid Until:
21 JUNE 2021

This is to certify that the management system of:

Wellmed International Industries Pvt. Ltd.

A-176 & 177, Sector - 63, Noida -201301, U.P., India.

Complies with the requirements of:

ISO 13485:2016/NS-EN ISO 13485:2016

The Certificate is valid for the following scope:

Development, Manufacture, Marketing of Disposable Medical Devices for Infusion, Gastroenterology, Urology, Surgery, Anaesthesia and Allied Applications.

Place and Date:
Høvik, 22 May 2018



For:
DNV GL NEMKO PRESAFE AS

Eugenie Winger Husebye

Eugenie Winger Husebye

The Certificate has been digitally signed.
See 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.



DNV BUSINESS ASSURANCE

EC CERTIFICATE - FULL QUALITY ASSURANCE SYSTEM

Certificate No. 94308-2011-CE-IND-NA 1.0

This Certificate consists of 4 pages

This is to certify that the Quality Management System of

Wellmed International Industries Pvt. Ltd.

A- 176 & 177 Sector 63 Noida 201301 U.P India

for design, production and final product inspection/testing of

Sterile Medical Disposable 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, 01 April 2016

This Certificate is valid until:

11 April 2021

For DNV GL BUSINESS ASSURANCE
NORWAY AS



Tone Kolpus
Certification Manager

Notified Body No.:
0434

Aud Løken Eiklid
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.



Cert. No.: 94308-2011-CE-IND-NA
Rev. No.: 1.0
Project No.: PRJC-291893-2011-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
0	Original certificate	2011-04-11
1	Recertification Audit	2016-04-11

Products covered by this Certificate

Product Description	Product	Class
Sterile Disposable Medical Devices		
<u>Transfusion & Infusion:</u>		
I.V Cannula	I.V. Cannula with/without Injection port & with/without wings Size: 14,16,17,18,20,22,24 & 26 G I.V. Cannula with wings & without Injection port for Neonates with & without wing holder Size: 24 & 26 G I.V. Cannula with Suturable wings & Flip Type port Size: 14,16,17,18,20,22,24 & 26 G I.V. Cannula with wings & Three Way Size: 14,16,17,18,20,22,24 & 26 G I.V. Cannula Pen Type with & without rigid plastic enclosure Size: 14,16,17,18,20,22,24 & 26 G SAFETY I.V. Cannula with needle bevel enclosure & with complete needle enclosure Size: 14,16,17,18,20,22,24 & 26 G	IIa
Three Way Stop Cock	Normal Pressure, High Pressure, Normal Pressure with Ext. Line, High Pressure with Ext. Line	IIa
Three Way Stop Cock (Lipid Resistant)	Normal Pressure, High Pressure, Normal Pressure with Ext. Line, High Pressure with Ext. Line	IIa
I.V Flow Regulator	Standard	IIa
Obtuator	Size: 14,16,17,18,20,22,24 & 26 G	IIa
Heparin Port/ Injection Stopper	Latex/ Silicone Transparent and Opaque	IIa
Luer Lock/ Threaded Stopper/ Luer Cap	Standard	IIa



Cert. No.: 94308-2011-CE-IND-NA
Rev. No.: 1.0
Project No.: PRJC-291893-2011-PRC-IND

I.V Set	Burette Type: 110, 150 ml Vented: Micro/Macro Drop Non Vented: Micro/Macro Drop	Ila
Extension Tube	Extension Tube(Normal) , High Pressure	Ila
<u>Gynaecology:</u>		
Amniotic Sac Perforator	Standard	Ila
Umbilical Cord Clamp		Is
<u>Urology:</u>		
Foley Balloon Catheter	Two Way / Three way Size FG 06 to 24	Ila
Nelaton Catheter	FG: 8 to 22	Ila
<u>Gastroenterology:</u>		
	Ryle's Tube: FG: 8,10,12,14,16,18,20,22 Levins Tube FG: 8,10,12,14,16,18,20,22,24 Infant Feeding Tube FG: 4,5,6,7,8,10	Ila
<u>Anaesthesia & Respiratory</u>		
	Endotracheal Tube with/ without Cuff 02 to 11 m.m Nebulizer: with /without Face Mask(Adult and Child) Suction Catheter: Plain, Finger Tip Control, Thumb Control FG: 6 to 22 Nasal Oxygen Catheter FG: 06 to 22 Mucus Extractor Size: FG 10 to 14	Ila
<u>Anaesthesia & Respiratory</u>	Face Mask: (Adult and Child), Face Mask with NRB(Adult & Child) Twin Bore Nasal Oxygen Set: (Adult& Child) Guedal Airway Size: 000,00,0,1,2,3,4,5,6	Is
<u>Surgery& Wound Drainage</u>		
Chest Drainage Catheter(Thoracic Drainage Catheter)	Straight, Curved FG: 06 to 40	Ila
Chest Drainage Catheter with Trocar(Thoracic Drainage Catheter with Trocar)	FG: 06 TO 40	Ila
Closed Wound Suction Drainage Set:	FG:8 ,10,12,14,16,18 with Bellow capacity 50 ml,400 ml, 800 ml	Ila



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Redon Drain	Size FG: 8 to 20	Ila
Yankauer Suction Set	Standard/ Crown Tip with or Without Vacuum Control	Ila
Corrugated Drainage Sheet	Size: 25x 250 m.m	Ila
A.V. Fistula Needle	Fixed and Rotating Wings Size: 15 to 17 G	Ila

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

Sites covered by this certificate

Site Name	Address
Wellmed International Industries Pvt. Ltd.	A- 176 & 177 Sector 63 Noida 201301 U.P India

EU Representative : CMC Medical Devices & Drugs S. L.
C/Horacio Lengo, N° 18 CP 29006, Málaga, Spain
Ph: + 34951214054

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



DNV BUSINESS ASSURANCE



CERTIFICAT CE – SISTEM COMPLET DE ASIGURARE A CALITĂȚII
Certificat Nr. 94308-2011-CE-IND-NA 1.0

Acest Certificat conține 4 pagini
*Se certifică prin prezenta că Sistemul de Management al
Calității al companiei*

Wellmed International Industries Pvt. Ltd.

A- 176 & 177 Sector 63 Noida 201301 U.P India

pentru proiectare, producție și inspecție/ testare finală de

Dispozitive medicale sterile de unică folosință

a fost evaluat cu privire la
procedura de evaluare a conformității, descrisă în Articolul 11.3.a și Anexa II, excluzând secțiunea 4
(Modul H) la Directiva Consiliului 93/42/CEE pentru Dispozitive Medicale, amendată, și s-a
constatat că este în conformitate

Detalii suplimentare pe verso

Locul și data:

Høvik, 01 Aprilie 2016

Acest Certificat este valabil până la:

11 Aprilie 2021

Ptr. DNV GL BUSINESS ASSURANCE
NORWAY AS



Tone Kolpus
Director Certificare

Organism Notificat nr:
0434

Aud Løken Eiklid
Revizor Tehnic

Acest Certificat poartă semnătura digitală. vezi www.dnv.com/digitalsignatures pentru mai mult informații

Aviz: *Certificatul este supus termenilor și condițiilor de pe verso. Orice schimbări semnificative în design și construcție pot anula acest certificat.*

În cazul unor pierderi sau daune suferite de o persoană, dovedite a fi fost cauzate de un act neglijent sau omisiune din partea Det Norske Veritas, atunci Det Norske Veritas va plăti despăgubiri acestei persoane pentru pierderea sau dauna directă dovedită. Cu toate acestea, despăgubirea nu va depăși o sumă egală cu de zece ori taxa percepută pentru serviciul în chestiune, cu condiția ca valoarea maximă a compensației nu va depăși niciodată 300.000 USD. În această prevedere "Det Norske Veritas" va însemna Fundația Det Norske Veritas precum și toate sucursalele acesteia, directori, oficiali, angajați, agenți și oricare altă persoană care acționează în numele Det Norske Veritas.

Det Norske Veritas AS, Veritasveien 1, 1322 Høvik, Norvegia. Tel: +47 67 57 9900 Fax: +47 6757 9911 www.dnv.com



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Jurisdicție

Aplicarea Directivei Consiliului 93/42/CEE din 14 Iunie 1993, adoptată ca 'Forskrift for Medisinsk Utstyr' Ministerul Sănătății și Serviciilor Medicale din Norvegia.

Istoric Certificat

Revizie	Descriere	Data eliberării
0	Certificat Original	11.04.2011
1	Audit pentru recertificare	11.04.2016

Produse acoperite de acest Certificat

Descrierea produsului	Produs	Clasa
Dispozitive medicale sterile de unică folosință		
<u>Transfuzie & Infuzie:</u>		
I.V. Canulă	I.V. Canulă cu/ fără port de injecție & cu/ fără aripioare Mărime: 14,16,17,18,20,22,24 & 26 G I.V. Canulă cu aripioare & fără port de injecție pentru nou-născuți cu & fără suport cu aripioară Mărime: 24 & 26 G I.V. Canulă cu aripioare suturabile & port tip flip Mărime: 14,16,17,18,20,22,24 & 26 G I.V. Canulă cu aripioare & cu trei căi Mărime: 14,16,17,18,20,22,24 & 26 G I.V. Cannula tip stilou cu & fără carcasă de plastic rigidă Mărime: 14,16,17,18,20,22,24 & 26 G Canulă de siguranță I.V. cu carcasă țesută pentru ac & cu carcasă completă pentru ac Mărime: 14,16,17,18,20,22,24 & 26 G	Ila
Robinet cu trei căi	Presiune normală, Presiune ridicată, Presiune normală cu prelungitor, Presiune ridicată cu prelungitor	Ila
Robinet cu trei căi (rezistent la lipide)	Presiune normală, Presiune ridicată, Presiune normală cu prelungitor, Presiune ridicată cu prelungitor	Ila
Dispozitiv de reglare a fluxului I.V.	Standard	Ila
Obturator	Mărime: 14,16,17,18,20,22,24 & 26 G	Ila
Port heparină / Opritor injecție	Latex/ Silicon, Transparent și Opac	Ila
Sistem de închidere Luer Lock/ Opritor filetat/ Capac Luer	Standard	Ila



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Set I.V.	Tip biuretă: 110, 150 ml Ventilat: Cu micro/macro-picătură Neventilat: Cu micro/macro-picătură	Ia
Tub extensie	Tub extensie (Normal), Presiune ridicată	Ia
<u>Ginecologie:</u>		
Perforator sac amniotic	Standard	Ia
Clemă cordon ombilical		Is
<u>Urologie:</u>		
Cateter cu balon Foley	Două căi/ Trei căi Mărime FG 06 la 24	Ia
Cateter Nelaton	FG: 8 la 22	Ia
<u>Gastroenterologie:</u>		
	Tub Ryle: FG: 8,10,12,14,16,18,20,22 Tub Levins FG: 8,10,12,14,16,18,20,22,24 Tub alimentare sugar FG: 4,5,6,7,8,10	Ia
<u>Anestezie & Respirator</u>		
	Tub endotraheal cu/ fără garnitură 02 la 11 m.m Nebulizator: cu / fără mască (Adulți și Copii) Cateter absorbție: Drept, Control vârf deget, Control degetul mare FG: 6 la 22 Cateter nazal pt oxigen FG: 06 la 22 Extractor mucus, Mărime: FG 10 la 14	Ia
<u>Anestezie & Respirator</u>	Mască: (Adulți și Copii), Mască cu NRB (Adulți și Copii) Set nazal pt oxigen cu dublu orificiu: (Adulți și Copii) dispozitiv pentru căile respiratorii Guedel, Mărime: 000,00,0,1,2,3,4,5,6	Is
<u>Chirurgie & Drenaj plagă</u>		
Cateter drenaj toracic (Cateter toracic)	Drept, curbat FG: 06 la 40	Ia
Cateter drenaj toracic cu Trocar (Cateter toracic cu Trocar)	FG: 06 la 40	Ia
Set de drenaj închis cu aspirația plăgii:	FG:8 ,10,12,14,16,18 cu capacitate Bellows 50 ml,400 ml, 800 ml	Ia



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Tub dren Redon	Mărime FG: 8 la 20	Ila
Set de absorbție Yankauer	Vârf standard/ coroană cu sau fără control vid	Ila
Foaie corugată de drenaj	Mărime: 25x 250 m.m	Ila
Ac fistulă A.V.	Aripioare fixe și rotative Mărime: 15 la 17 G	Ila

Lista completă a dispozitivelor este depusă la Organismul Notificat.

Unități acoperite de acest certificat

Denumire unitate	Adresa
Wellmed International Industries Pvt. Ltd.	A- 176 & 177 Sector 63 Noida 201301 U.P India

Reprezentanță UE : CMC Medical Devices & Drugs S. L.
C/Horacio Lengo, N^o 18 CP 29006, Málaga, Spania,
Tel: + 34951214054

Termeni și condiții

Certificatul este supus următoarelor condiții și termeni:

- Orice producător (vezi 2001/95/CE pentru o definiție exactă) este responsabil pentru daunele cauzate de un defect în produsul(ele) său(sale), în conformitate cu Directiva 85/374/CEE, amendată, privind răspunderea produselor defecte.
- Certificatul este valabil doar pentru produsele și/ sau unitățile de producție specificate mai sus.
- Producătorul va îndeplini obligațiile rezultate din sistemul de calitate aprobat și va menține acest sistem adecvat și eficient.
- Producătorul va informa Oficiul local DNV cu privire la orice actualizare intenționată a sistemului de calitate și DNV va evalua schimbările și va decide asupra valabilității certificatului.
- Vor fi efectuate audituri periodice pentru a verifica dacă Producătorul menține și aplică sistemul de calitate. DNV își rezervă dreptul, pe baza unui motiv precis sau în urma unei suspiciuni, de a efectua vizite neanunțate.

Următoarele pot anula acest Certificat:

- Schimbări în sistemul de calitate, care afectează producția.
- Auditurile periodice nu sunt efectuate în intervalul permis.

Declarație de conformitate și marcarea produsului

Dacă sunt întrunite condițiile și termenii de mai sus, producătorul poate întocmi o declarație de conformitate CE și poate aplica legal marca CE urmată de numărul de identificare DNV al Organismului Notificat.

SFÂRȘITUL CERTIFICATULUI

