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Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
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Product Service

# EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)

(Devices in Class IIa, IIb or III)

**No. G1 041938 0007 Rev. 00**

**Manufacturer:**

**POLY MEDICURE LIMITED**

Plot No. 104-105, Sector-59

HSI IDC Industrial Area, Ballabhgarh

Faridabad, Haryana 121004

INDIA

**Product Category(ies):**

IV Cannula/ Catheter with / without Safety Features, Infusion Sets, Burette Infusion Sets, Flow Regulators, Extension Lines, Luer Caps, Stylet (Obturator), CVP Manometers, Stop cock with/without extension line, Needle free connectors with/without extension line, Scalp vein (Winged Infusion) Set (with / without safety features), Insulin Syringe, Huber Infusion set with / without safety features, Over the Needle (OTN) Catheter, Arterial Cannula with/without Safety Features, Manifolds with/without Extension line, Mini-midline Catheter (Peripheral catheter), Transfusion Pump Set, Luer Adaptors, Blood Bags, Blood Collection Set with / without Safety Features, Blood Collection Needle & Holder, Transfusion Sets (BT Sets), Closed Wound Suction Unit, Yankaur Suction Set (Suction tube and/or Handle), Thoracic Drainage Catheter (with/without Trocar), Redon Drainage Tube, Abdominal Drainage Set, Under Water Seal Drainage System, Female catheter, Nelaton catheter, Foley Balloon Catheter, Irrigation Set, Levins tube, Infant Feeding Tube, Ryle's Tube, Stomach Tube, Umbilical Catheter, Feeding Bag, Mucus Extractor with/without Bacterial Filter, Suction Catheter, Nasal Oxygen Catheter/ Cannula, Oxygen Catheter, Guedel Airways, Endotracheal Tubes (Plain, Cuffed, Reinforced), Catheter Mount, Oxygen Mask, Nebulizer Mask, Venturi Mask, Blood Line Set, Fistula Needle with / without Safety features, Peritoneal Dialysis Transfusion Set, Peritoneal Dialysis Catheter Kit, High Pressure Vacuum Drainage Bottle.

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

**Report No.:** IND2019081\_CN

**Valid from:** 2020-06-17

**Valid until:** 2024-05-26

**Date,** 2020-06-17

Christoph Dicks

Head of Certification/Notified Body



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## Confirmation Statement related to the EC Certificate (MDD)

List of Sites involved in the Product Realisation Processes

**No. GDS 041938 0009 Rev. 00**

**Manufacturer:**

**POLY MEDICURE LIMITED**

Plot No. 104-105, Sector-59  
HSIIDC Industrial Area, Ballabhgarh  
Faridabad, Haryana 121004  
INDIA

This List of Sites is only  
valid in combination with the  
following EC Certificate (MDD):

**G1 041938 0007 Rev. 00**

The following pages list all sites under the manufacturer's quality system where product realisation processes are conducted for those devices covered by the aforementioned EC Certificate pursuant to the Directive 93/42/EEC (MDD) concerning medical devices.

**Report No.:** IND2019081\_CN

**Valid until:** 2024-05-26

**Issue Date:** 2020-06-19

( Randolph Köhler )  
PS-MHS-FA-0 – Foreign Affairs



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## Confirmation Statement related to the EC Certificate (MDD)

List of Sites involved in the Product Realisation Processes

**No. GDS 041938 0009 Rev. 00**

### Sites:

POLY MEDICURE LIMITED  
Plot No.115-116, Sector-59, HSIIDC Industrial Area, Ballabhgarh,  
Faridabad, Haryana 121004, INDIA

POLY MEDICURE LIMITED  
Unit III: Plot No. 17, Sector-3, SIDCUL, Integrated Industrial  
Estate, Haridwar, Uttarakhand 249403, INDIA

POLY MEDICURE LIMITED  
Plot No. 104-105, Sector-59, HSIIDC Industrial Area, Ballabhgarh,  
Faridabad, Haryana 121004, INDIA