



Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
www.zlg.de  
ZLG-BS-244.10.08



Product Service

# EC Certificate

Full Quality Assurance System

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

(Devices in class I in sterile conditions, sterilized systems or procedure packs)

**No. G1S 041938 0003 Rev. 00**

## Manufacturer:

## POLY MEDICURE LIMITED

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

## Product Category(ies):

Vial access spike, Umbilical Cord Clamp, Urine Collection Bag, Rectal  
Catheter, Trans Urethral Resection Set (TUR Set), Sterile bottle caps.

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex II. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

**Report No.:** IND2019081

**Valid from:** 2020-06-01

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

**Date,** 2020-06-01

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