



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
HSI IDC 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



Product Service

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



Product Service

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