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Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
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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 109029 0001 Rev. 00**

## Manufacturer:

**Disposafe Health and Life Care Limited**

Plot No.1&2, Phase II, Sector-59, Ballabhgarh

Faridabad, Haryana 121004

INDIA

## Product Category(ies):

IV Cannula, Three way stop cock with/without extension tube, IV Administration Set, Injection stopper, Luer Cap, Hypodermic Needle & Disposable Syringes of all variants, Flow regulator set with/without "Y" Site, Extension tube with all variants, Measured Volume Set, Blood Transfusion Set, Blood Collection Set with/without Safety Features, Foley Balloon Catheter, Nasogastric Tube (Ryle's Tube/Levins Tube/Salem Sump Tube/Feeding Tube), Mucus Extractor, Suction Catheter, Endotracheal tube with all variants, Wound Drainage Set with all variants, Surgical Gloves, Karman Cannula, Nasal Oxygen Catheter/Cannula, AV Fistula Needle Set with all variants, Scalp vein set with/without safety features, Yankauer Handle with tube set, Surgical Blades in Carbon Steel and Stainless Steel, Dermal Curette, Prep Razor, Disposable scalpel with/without safety features, Gouge Blades in Carbon Steel and Stainless Steel, Stitch Cutter in Carbon Steel and Stainless Steel, Biopsy Punches, IV Cannula with integrated three-way stop cock, Safety IV Cannula, Blood Lines Set, Tracheostomy Tube with all variants.

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. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:G11090290001Rev.00](http://www.tuvsud.com/ps-cert?q=cert:G11090290001Rev.00)

**Report No.:**

IND2020075

**Valid from:**

2021-05-20

**Valid until:**

2024-05-26

**Date,** 2021-05-20

Christoph Dicks

Head of Certification/Notified Body