



Ref: DOC/IVC/01, Rev: 00

Date: 21-05-2021

### Declaration of Conformity

**Manufacturer:**

Name: DISPOSAFE HEATH AND LIFE CARE LIMITED

Plot no. 1&2, Sector -59, Phase -II,  
Ballabgarh,-121004,Haryana(India)

Phone:0129-4170201,4160201

Fax:+91-11-46540320

Email:info@disposafe.com

Web:www.disposafe.com

Ballabgarh,-121004

**Product: IV Cannula**

S.no	Product	Description	Brand Name	Size	UMDNs Code	Classification /Rule
1.	IV Cannula	With wings & with port	Dispoflon	14G,16G,17G,18G,20G,22G,24G,26G	10727	Ila/7
2.	IV Cannula	With wings & without port	Dispowing	14G,16G,17G,18G,20G,22G,24G,26G	10727	Ila/7
3.	IV Cannula	Without wings & without port	Dispoway	14G,16G,17G,18G,20G,22G,24G,26G	10727	Ila/7
4.	IV Cannula with Safety Features		Disposafe	14G,16G,17G,18G,20G,22G,24G	10727	Ila/7

**European Representative:**

Name: CEpartner4U BV

Address: ESDOORNLAAN 13, 3951 DB MAARN, Netherlands

Classification: Ila (Rule-7 Annex IX, MDD 93/42/EEC-A2:2007)

**Conformity Assessment Route:** According to annex II (excluding section IV) of the council directive 93/42/EEC of 14<sup>th</sup> June 1993 concerning medical devices, latest revision.

**List of Applicable Standard :** ENISO10555-1:2013,ISO10555-5:2015 ,EN ISO11135:2014,ENISO11607,ENISO10993-1:2018  
ENISO1138-2:2008,ENISO15223-1:2016,ISO80369-7:2017

Are in conformity with the essential requirement and provisions of the Council Directive 93/42/EEC & are subject to the procedure set out in Annexure-II excluding Section 4 (Module H2) of the EC Directive 93/42/EEC on medical devices under the supervision of the **Notified Body TUV-SUD Product Services GmbH, Germany with CE 0123.** We also hereby declare that the manufacturer is exclusively responsible for the Declaration of conformity.

**EC Certificate No. G1 109029 0001 Rev.00 Valid until :2024-05-26**

Company undertakes to notify any malfunction/deterioration of the performance of the device to the appropriate authority and shall recall such devices already placed in the market. We hereby appoint CEpartner4U B.V. ESDOORNLAAN 13, 3951 DB MAARN, the Netherlands to act as European Authorized Representative

**Notified Body : TUV-SUD Product Services GmbH**

**(EC) Certificate (S) : CE0123**

**Start of CE-Marking :- -----**

**Place, Date of Issue : Ballabgarh-Faridabad , 21-05-2021**

**Signature:**

**Name: Vijay Kumar**  
**Position (DGM- Regulatory Affairs & MR )**



### **Disposafe Health and Life Care Ltd.**

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