



(Sample DOC)

Ref: DOC/Prima /01, Rev: 00

Date: 15-12-2021

Declaration of Conformity

Manufacturer:

Name: DISPOSAFE HEALTH AND LIFE CARE LIMITED
Plot no. 1&2, Phase –II, Secor-59
Ballabgarh, Faridabad, Haryana-121004
Phone: 0129-4170201, 4160201
Fax: +91-11-46540320
Email: info@disposafe.com
Web: www.disposafe.com

Product Brand: Prima: Surgical Blade

European Representative:

Name: CE partner 4U BV
Address: ESDOORNLAAN 13, 3951 DB MAARN, Netherlands
Classification: IIa (Rule-2 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 14th June 1993 concerning medical devices, latest revision.

List of Applicable Standard : EN ISO 11135:2014, EN ISO 11607, EN ISO 10993-1:2018, EN ISO 1138-2:2008, EN ISO 15223-1:2016, ISO 80369-7:2017.

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.

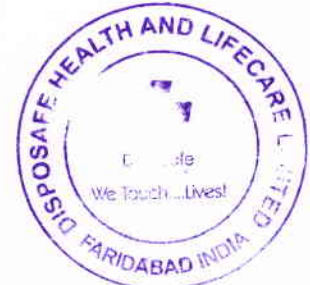
EC Certificate No. G1 109029 0001 Rev.00 Valid until :2024-05-26

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 CE partner 4U 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 : 20/05/2021
Place, Date of Issue : Ballabgarh, Faridabad , 15-12-2021

Signature:


Name: JITESH BANGIA
Position: Sr Manager QA/ RA & MR)



Disposafe Health and Life Care Limited

CIN NO. U27310DL2007PLC171561

Registered Office :

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New Delhi-110024, INDIA

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Manufacturing :

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