Disposafe™
We Touch.... Lives!

Ref:DOC/01,Rev:00

Declaration of Conformity

Date: 07-07-2023

Manufacturer:
Name: DISPOSAFE HEALTH AND LIFE CARE LIMITED
Registered Trademark: ----NA
Manufacturer SRN No - IN-NF-000020265
Authorized Representative SRN No - NL-AR-000000111
Phone No. : 0129-4170201, 4160201,
Fax: +91-11-46540320
Plot no: 1&2, Phase –II, Secor-59, Ballabhgarh, Faridabad, Haryana-121004
Email: info@disposafe.com
Web: www.disposafe.com

S.no	Name	Gauges	Intended Use	GMDN Code	Classification/Rule	Trade Name	First Date of CE Compliance
1.	Surgical Blades	10,10A,11,11P,12,12B/12D,14,15,15T,15C,16,18,19,20,21,22,23,24,25	Intended for use as a cutting device during surgical, pathology and minor medical procedures. It is used for tissue separation and other procedure that require a sharp blade to puncture and cut.	37445	IIa/6	Prima	20.05.2021

Notified Body : TUV-SUD Product Services GmbH
(EC) Certificate (S) : CE0123
Start of CE-Marking : 20.05.2021
EC Certificate No : G1109029 0001 Rev.00 Valid until :2024-05-26
Conformity Assessment Route: Are in conformity with the essential requirement and provisions of the Council Directive 93/42/ ECC & are subject to the procedure set out in Annexure-II excluding section 4 (Module H2) of the EC Directive 93/42 ECC on medical devices, latest revision EN ISO 80369-7:2016, EN ISO 14644-1:2015, EN ISO 15223-1:2021, EN ISO 11135:2014/And 1:2018, EN ISO 11138-1:2017, EN ISO 11737-1:2018, EN ISO 11607-1:2019, EN ISO 11138-2:2017, EN ISO 10993-5:2009, EN ISO 10993-10:2010, EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 14698-1:2003, EN ISO 14698-2:2003

European Representative:
Name: CE partner 4U BV
Address: ESDOORNLAAN 13, 3951 DB MAARN, Netherlands

We also hereby declare that the manufacturer is exclusively responsible for the Declaration of conformity. 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.

Place: Ballabhgarh, Faridabad
Date of Issue : 07-07-2023

DISPOSAFE HEALTH AND LIFE CARE LTD.

(Authorized Signatory)