EC Declaration of Conformity

for RUCK Sterile Surgical Blade

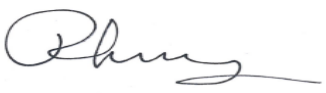
The undersigned declares under its sole responsibility that the medical devices described in this declaration conform to the requirements of Council Directive 93/42/EEC concerning medical devices, as amended by Directive 2007/47/EC, and as transposed into the national law of the Member States.

The above-mentioned medical devices are placed on the market in accordance with Article 120 of Regulation (EU) 2017/745 (MDR) and continue to comply with Council Directive 93/42/EEC during the applicable transitional period.

The undersigned declares that the products described in this document meet the Council Directive provisions that apply to them and the CE Mark may be affixed.

General Product Name:	Surgical Blades (Sterile) in Carbon Steel & Stainless Steel
Legal Manufacturer: (Name on Label)	**ADITYA DISPOMED PRODUCTS PRIVATE LIMITED** Plot No 19, Sector 6 IMT Manesar, Gurgaon-122050, Haryana, India E-mail: info@adityadispomed.com Website: www.adityadispomed.com
SRN No.	IN-MF-000020014
Variants:	As per Annex II (This document) – Product Listing
Intended Use:	These are used for surgery after mounting on Metal B.P. Handles.
MD Directive Classification:	Class IIa as per Rule 6 of annex IX of MDD 93/42/EEC as amended by 2007/47/EC
GMDN Code	37445
Notified Body and CE:	DNV Product Assurance AS, (2460) Veritasveien 1, 1363 Høvik, Norway Phone : +47 67578800 E-mail: infodnvpa@dnv.com Website : www.dnv.com
CE Certificate & Validity	11174-2017-CE-IND-NA-PS Rev. 2.0 dated 18th December 2020 validity extended upto 31st December 2028 as per Notified Body Confirmation Letter Reference C670077 dated 07-02-2024
EU Authorised Representative:	MDSS GmbH Schiffgraben 41, 30175 Hannover Germany Phone: +49 511 6262 8630 E-mail: info@mdssar.com
Medical Device Directive Assessment Route:	Notified Body Certification according to Annex II excl. section 4 & Article 11 of the MDD 93/42/EEC & as amended directive 2007/47/EC concerning medical devices.
Applicable Standards	As per Annex I (This document) – Applicable Standards

Name Rakesh Marwah **Position** Head QA/RA

Signature  **Date** 14-04-2026

Annex I – Applicable Standards

This present declaration is also in conformity with the following Product standard

EN 27740:1992 / ISO 7740:1985	Instruments for surgery, scalpels with detachable blades, fitting dimensions

Harmonized EN Standards

These demonstrate conformity with MDR GSPRs.

S. No.	***No. Of Standard***	***S. No.***	***No. Of Standard***
1	EN ISO 13485:2016/A11:2021	11	EN ISO 11607-2:2020
2	EN ISO 14971:2019/A11:2021	12	EN ISO 11137-1:2015/A2-2019
3	EN ISO 10993-1: 2020	13	EN ISO 11137-2:2015
4	EN ISO 10993-4: 2017	14	EN ISO 11137-3:2017
5	EN ISO 10993-5:2009	15	EN ISO 20417:2021
6	EN ISO 10993-10: 2023	16	EN ISO 11737-1:2018/A1:2021
7	EN ISO 10993-11: 2018	17	EN ISO 11737-2:2020
8	EN ISO 10993-12: 2021	18	EN ISO 15223-1:2021
9	EN ISO 10993-23:2021	19	EN ISO 62366-1:2015/A1:2020
10	EN ISO 11607-1:2020	20	EN ISO 11140-1:2009

Other Applicable / Supporting Standards

These support manufacturing environment, testing or validation, but are not device standards.

S. No.	***No. Of Standard***	***S. No.***	***No. Of Standard***
1	ISO 14644-1:2015	10	ISO 14698-1:2003
2	ISO 14644-2:2015	11	ISO 14698-2 2003
3	ISO 14644-3:2019	12	ISO 6507-1:2023
4	ISO 14644-4:2022	13	ASTM F88-15
5	ISO 14644-5:2025	14	ASTM F1980 -21
6	ISO 14644-7:2004	15	EN 868-5
7	ISO 14644-8:2013	16	BS 5194-1:1991
8	ISO 14644-9:2012	17	IS 10150: 1981
9	ISO 14644-10:2013		

Annex II– Product Listing

Reference No	Description	Size	UDI
2009010	Ruck Sterile Carbon Steel Surgical Blade box 100	10	08902895291100
2009013	Ruck Sterile Carbon Steel Surgical Blade box 100	13	08902895291131
2009015	Ruck Sterile Carbon Steel Surgical Blade box 100	15	08902895291155
2009019	Ruck Sterile Carbon Steel Surgical Blade box 100	19	08902895291193
2009020	Ruck Sterile Carbon Steel Surgical Blade box 100	20	08902895291209
2009021	Ruck Sterile Carbon Steel Surgical Blade box 100	21	08902895291216