


Declaration of Conformity



According to Annex - II excluding section 4 of Council Directive 93/42/EEC on Medical Devices, as amended.

We at  Aditya Dispomed Products Pvt. Ltd, Plot No 19, Sector 6 IMT Manesar Haryana 122050, India declare under our sole responsibility that the products covered under general surgical disposable.

Brand Name : RUCK SKALPELLKLINGEN CE 2460

PRODUCT: Following products (medical devices), Sterile in CARBON STEEL

Description of the Medical device		Model/Variants		Medical Device Class	
RUCK BRAND SWISS CARBON STEEL GAMMA STERILE SURGICAL BLADE IN OEM PACKING, CE 2460. 100/BOX		10, 15, 20,		Rule	Class
				6	II a
Batch No		Date of Expiry		Qty Produced	
Y01656		May-2026		800,000 Pcs	
Y01648		May-2026		300,000 Pcs	
Y01655		May-2026		150,000 Pcs	

Comply with the essential requirement and other relevant requirement of MDD 93/42/EEC. Manufacturer is exclusively responsible for the declaration of conformity, this declaration is based on the full/partial compliance of standards as available in Section 7 of TF-01 (List Attached)

APPLICABLE PRODUCT STANDARD : List Attached

SPECIFICATION : SS 7.2-01 Specifications Sheet of Kiato + Premium Sterile Surgical Blade made from Carbon & Stainless Steel

NOTIFIED BODY : DNV GL Presafe AS, Veritasveien 3, 1363 Hovik Post Box 161, N-1300, Sandvika
Phone + 4767579900

CE Certificate No. : 11174-2017-CE-IND-NA-PS Rev. 2.0. dated 18 December 2020 valid till 27 May 2024.

EC	REP
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Medical Device Safety Service GmbH, Schiffgraben 41, 30175 Hannover, Germany
Phone: +49 511 6262 8630

Date 10-07-2021
Place: Gurgaon India

Name : Rakesh Marwah
Job Title : Management Representative

F 7.2-21 Rev 3

Aditya Dispomed Products Pvt. Ltd.
Plot No. 19, Sector - 6 , IMT Manesar, Haryana - 122050 INDIA
Tel: + 91 124 2291406/7/8 Fax: +91 124 2291204

Annex
List of Applicable Standard


S.No.	No. of standard	S.No.	No. of standard
1.	EN ISO 13485:2016,	2.	EN ISO 11607-2:2006,
3.	ASTM F 1980-16,	4.	EN ISO 11737-1:2006,
5.	ASTM F 88-15,	6.	EN ISO 11737-2:2009,
7.	BS 2982:1992,	8.	ISO 6507-1 2018
9.	BS 5194:1991,	10.	EN ISO 14155:2011,
11.	BS EN 62366-1:2015,	12.	EN ISO 15223-1:2016,
13.	BS EN ISO 10993-10:2013,	14.	EN ISO 14971:2012,
15.	EN 1041:2008,	16.	EN-868-5:2018,
17.	EN 1422:1997+ A1:2009,	18.	IS 10500-1991,
19.	EN 27740:1992,	20.	IS 245-1988,
21.	EN ISO 10993-04: 2009,	22.	IS-10150:1981,
23.	EN ISO 10993-1:2009,	24.	IS-6263-1972,
25.	EN ISO 10993-11: 2009,	26.	ISO 6507-3: 2018
27.	EN ISO 10993-12: 2012,	28.	ISO 11137-3:2017,
29.	EN ISO 10993-13:2010,	30.	ISO 11737-1:2018,
31.	EN ISO 10993-15:2009,	32.	ISO 11140-1:2014,
33.	EN ISO 10993-16:2010,	34.	ISO 14644-1:2015,
35.	EN ISO 10993-17:2009,	36.	ISO 14644-10:2013,
37.	EN ISO 10993-18:2009,	38.	ISO 14644-2:2015,
39.	EN ISO 10993-5:2009,	40.	ISO 14644-3:2005,
41.	EN ISO 10993-7-2008,	42.	ISO 14644-4:2001,
43.	EN ISO 11140-1:2009,	44.	ISO 14644-5:2004,
45.	EN ISO 11137-1:2015,	46.	ISO 14644-7:2004,
47.	EN ISO 11137-2:2015,	48.	ISO 14644-8:2013,
49.	EN ISO 11138-2:2009,	50.	ISO 14155: 2011
51.	EN ISO 11607-1:2009 + A1:2014		

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				6	II a
Batch No		Date of Expiry		Qty Produced	
Y01656		May-2026		800,000 Pcs	
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Comply with the essential requirement and other relevant requirement of MDD 93/42/EEC. Manufacturer is exclusively responsible for the declaration of conformity, this declaration is based on the full/partial compliance of standards as available in Section 7 of TF-01 (List Attached)

APPLICABLE PRODUCT STANDARD : List Attached

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NOTIFIED BODY :	DNV GL Presafe AS, Veritasveien 3, 1363 Hovik Post Box 161, N-1300, Sandvika Phone + 4767579900		
CE Certificate No. :	11174-2017-CE-IND-NA-PS Rev. 2.0. dated 18 December 2020 valid till 27 May 2024.		
<table border="1"><tr><td>EC</td><td>REP</td></tr></table>	EC	REP	Medical Device Safety Service GmbH, Schiffgraben 41, 30175 Hannover, Germany Phone: +49 511 6262 8630
EC	REP		

Date 10-07-2021
Place: Gurgaon India

Name : Rakesh Marwah
Job Title : Management Representative

F 7.2-21 Rev 3

Aditya Dispomed Products Pvt. Ltd.
Plot No. 19, Sector - 6 , IMT Manesar, Haryana - 122050 INDIA
Tel: + 91 124 2291406/7/8 Fax: +91 124 2291204

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7.	BS 2982:1992,	8.	ISO 6507-1 2018
9.	BS 5194:1991,	10.	EN ISO 14155:2011,
11.	BS EN 62366-1:2015,	12.	EN ISO 15223-1:2016,
13.	BS EN ISO 10993-10:2013,	14.	EN ISO 14971:2012,
15.	EN 1041:2008,	16.	EN-868-5:2018,
17.	EN 1422:1997+ A1:2009,	18.	IS 10500-1991,
19.	EN 27740:1992,	20.	IS 245-1988,
21.	EN ISO 10993-04: 2009,	22.	IS-10150:1981,
23.	EN ISO 10993-1:2009,	24.	IS-6263-1972,
25.	EN ISO 10993-11: 2009,	26.	ISO 6507-3: 2018
27.	EN ISO 10993-12: 2012,	28.	ISO 11137-3:2017,
29.	EN ISO 10993-13:2010,	30.	ISO 11737-1:2018,
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33.	EN ISO 10993-16:2010,	34.	ISO 14644-1:2015,
35.	EN ISO 10993-17:2009,	36.	ISO 14644-10:2013,
37.	EN ISO 10993-18:2009,	38.	ISO 14644-2:2015,
39.	EN ISO 10993-5:2009,	40.	ISO 14644-3:2005,
41.	EN ISO 10993-7-2008,	42.	ISO 14644-4:2001,
43.	EN ISO 11140-1:2009,	44.	ISO 14644-5:2004,
45.	EN ISO 11137-1:2015,	46.	ISO 14644-7:2004,
47.	EN ISO 11137-2:2015,	48.	ISO 14644-8:2013,
49.	EN ISO 11138-2:2009,	50.	ISO 14155: 2011
51.	EN ISO 11607-1:2009 + A1:2014		

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Description of the Medical device		Model/Variants		Medical Device Class	
RUCK BRAND SWISS CARBON STEEL GAMMA STERILE SURGICAL BLADE IN OEM PACKING, CE 2460. 100/BOX		10,		Rule	Class
				6	II a
Batch No		Date of Expiry		Qty Produced	
Y02390		Aug-2026		1,000,000 Pcs	

Comply with the essential requirement and other relevant requirement of MDD 93/42/EEC. Manufacturer is exclusively responsible for the declaration of conformity, this declaration is based on the full/partial compliance of standards as available in Section 9 of TF-01 (List Attached)

APPLICABLE PRODUCT STANDARD : List Attached

<u>SPECIFICATION</u> :	SS 7.2-01 Specifications Sheet of Kiato + Premium Sterile Surgical Blade made from Carbon & Stainless Steel
NOTIFIED BODY :	DNV Product Assurance AS, Veritasveien 3, 1363 Hovik, Norway, Phone + 4767578800 www.dnv.com
CE Certificate No. :	11174-2017-CE-IND-NA-PS Rev. 2.0. dated 18 December 2020 valid till 27 May 2024.
EC REP	Medical Device Safety Service GmbH, Schiffgraben 41, 30175 Hannover, Germany Phone: +49 511 6262 8630

Date 04-10-2021
Place: Gurgaon India

Name : Rakesh Marwah
Job Title : Management Representative

F 7.2-21 Rev 4

Aditya Dispomed Products Pvt. Ltd.

Plot No. 19, Sector - 6 , IMT Manesar, Haryana - 122050 INDIA

Tel: + 91 124 2291406/7/8 Fax: +91 124 2291204

List of Applicable Standard

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1	EN ISO 13485:2016	24	EN ISO 10993-18-2009
2	EN ISO14971:2012	25	EN ISO 15223-1:2016
3	ISO 14644-1 : 2015	26	EN ISO 11607-1 :2009 + A1:2014
4	ISO 14644-2 : 2015	27	EN ISO 11607-2 :2006
5	ISO 14644-4:2001	28	EN-868-5:2018
6	ISO 14644-5:2004	29	IS 10500-1991
7	IS-10150: 1981	30	IS 245-1988
8	EN ISO 11137-2:2015	31	ASTM F 1980 –16
9	ISO 11137-3:2017	32	ISO 6507-3 2018
10	ISO 11737-1 2018	33	ISO 6507-1 2018
11	EN ISO 11737-2:2009	34	ASTMF88-15
12	EN 27740: 1992	35	MEDDEV.2.7.1. Rev.4 - June 2016
13	BS 2982:1992	36	EN 1041:2008
14	EN ISO 10993-1:2009	37	BS EN 62366-1:2015
15	EN ISO 10993-04: 2009	38	ISO 14644-10:2013
16	EN ISO 10993-5: 2009	39	ISO 14644-3:2019
17	ISO 10993-10:2013	40	ISO 14644-7:2004
18	EN ISO 10993-11: 2009	41	ISO 14644-8:2013
19	EN ISO 10993-12: 2012	42	EN ISO 11140-1:2009
20	EN ISO 10993-13: 2010	43	ISO 14644-9:2012
21	EN ISO 10993-15:2009	44	BS 5194-1:1991
22	EN ISO 10993-16:2010	45	EN ISO 11137-1:2015/A2-2019
23	EN ISO 10993-17:2009	46	EN ISO 11737-1:2018/A1:2021