National Accreditation Board for Testing and Calibration Laboratories

SCOPE OF ACCREDITATION

Laboratory Name : SURETEX PROPHYLACTICS (INDIA) PRIVATE LIMITED, 74-91, KIADB INDUSTRIAL ESTATE, JIGANI II PHASE, BENGALURU, BENGALURU URBAN, KARNATAKA, INDIA

Accreditation Standard ISO/IEC 17025:2017

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Validity 28/01/2023 to 27/01/2025 **Last Amended on** -

S.No	Discipline / Group	Materials or Products tested	Component, parameter or characteristic tested / Specific Test Performed / Tests or type of tests performed	Test Method Specification against which tests are performed and / or the techniques / equipment used
Permanent Facility				
1	MECHANICAL-PERFORMANCE/DURABILITY/ SAFETY TEST	Natural Rubber Latex Male Condoms	Package Integrity of Individual Containers	ASTM D3078-02:
2	MECHANICAL-PERFORMANCE/DURABILITY/ SAFETY TEST	Natural Rubber Latex Male Condoms	Package Integrity of Individual Containers	Schedule - R of Drugs & Cosmetic Rules ,Paragraph 14
3	MECHANICAL-PERFORMANCE/DURABILITY/ SAFETY TEST	Natural Rubber Latex Male Condoms	Burst Pressure - Oven treated Condoms	ISO 4074, Annex H & I
4	MECHANICAL-PERFORMANCE/DURABILITY/ SAFETY TEST	Natural Rubber Latex Male Condoms	Burst Pressure - Oven treated Condoms	MERCOSUR/GMC/RES. No. 10, Attachment E & F
5	MECHANICAL-PERFORMANCE/DURABILITY/ SAFETY TEST	Natural Rubber Latex Male Condoms	Burst Pressure - Oven treated Condoms	RDC NO. 554, Annex VI & Annex V
6	MECHANICAL-PERFORMANCE/DURABILITY/ SAFETY TEST	Natural Rubber Latex Male Condoms	Burst Pressure - Oven treated Condoms	Schedule - R of Drugs & Cosmetic Rules, Paragraph 4(B), 9- Annexure V
7	MECHANICAL-PERFORMANCE/DURABILITY/ SAFETY TEST	Natural Rubber Latex Male Condoms	Burst Pressure - Untreated Condoms	ISO 4074, Annex H
8	MECHANICAL-PERFORMANCE/DURABILITY/ SAFETY TEST	Natural Rubber Latex Male Condoms	Burst Pressure - Untreated Condoms	MERCOSUR/GMC/RES. No. 10, Attachment E
9	MECHANICAL-PERFORMANCE/DURABILITY/ SAFETY TEST	Natural Rubber Latex Male Condoms	Burst Pressure - Untreated Condoms	RDC NO. 554, Annex V
10	MECHANICAL-PERFORMANCE/DURABILITY/ SAFETY TEST	Natural Rubber Latex Male Condoms	Burst Pressure - Untreated Condoms	Schedule - R of Drugs & Cosmetic Rules, Paragraph 4(B),9- Annexure IV
11	MECHANICAL-PERFORMANCE/DURABILITY/ SAFETY TEST	Natural Rubber Latex Male Condoms	Burst Pressure - Untreated Condoms	ASTM D3492, Annex A2
12	MECHANICAL-PERFORMANCE/DURABILITY/ SAFETY TEST	Natural Rubber Latex Male Condoms	Burst Volume - Oven treated Condoms	ISO 4074, Annex H & I
13	MECHANICAL-PERFORMANCE/DURABILITY/ SAFETY TEST	Natural Rubber Latex Male Condoms	Burst Volume - Oven treated Condoms	MERCOSUR/GMC/RES. No. 10, Attachment E & F

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14	MECHANICAL-PERFORMANCE/DURABILITY/ SAFETY TEST	Natural Rubber Latex Male Condoms	Burst Volume - Oven treated Condoms	RDC NO. 554, Annex VI & Annex V
15	MECHANICAL-PERFORMANCE/DURABILITY/ SAFETY TEST	Natural Rubber Latex Male Condoms	Burst Volume - Oven treated Condoms	Schedule - R of Drugs & Cosmetic Rules, Paragraph 4(B), 9- Annexure V
16	MECHANICAL-PERFORMANCE/DURABILITY/ SAFETY TEST	Natural Rubber Latex Male Condoms	Burst Volume - Untreated Condoms	ASTM D3492, Annex A2
17	MECHANICAL-PERFORMANCE/DURABILITY/ SAFETY TEST	Natural Rubber Latex Male Condoms	Burst Volume - Untreated Condoms	ISO 4074, Annex H
18	MECHANICAL-PERFORMANCE/DURABILITY/ SAFETY TEST	Natural Rubber Latex Male Condoms	Burst Volume - Untreated Condoms	MERCOSUR/GMC/RES. No. 10, Attachment E
19	MECHANICAL-PERFORMANCE/DURABILITY/ SAFETY TEST	Natural Rubber Latex Male Condoms	Burst Volume - Untreated Condoms	RDC NO. 554, Annex V
20	MECHANICAL-PERFORMANCE/DURABILITY/ SAFETY TEST	Natural Rubber Latex Male Condoms	Burst Volume - Untreated Condoms	Schedule - R of Drugs & Cosmetic Rules, Paragraph 4(B),9- Annexure IV
21	MECHANICAL-PERFORMANCE/DURABILITY/ SAFETY TEST	Natural Rubber Latex Male Condoms	Color Fastness	Schedule - R of Drugs & Cosmetic Rules, Paragraph 12
22	MECHANICAL-PERFORMANCE/DURABILITY/ SAFETY TEST	Natural Rubber Latex Male Condoms	Elongation at Break	ISO 4074, Annex J
23	MECHANICAL-PERFORMANCE/DURABILITY/ SAFETY TEST	Natural Rubber Latex Male Condoms	Force at Break	ISO 4074, Annex J
24	MECHANICAL-PERFORMANCE/DURABILITY/ SAFETY TEST	Natural Rubber Latex Male Condoms	Freedom from Holes	ASTM D3492 (Annex A3)
25	MECHANICAL-PERFORMANCE/DURABILITY/ SAFETY TEST	Natural Rubber Latex Male Condoms	Freedom from Holes	ISO 4074, Annex M
26	MECHANICAL-PERFORMANCE/DURABILITY/ SAFETY TEST	Natural Rubber Latex Male Condoms	Freedom from Holes	MERCOSUR/GMC/RES.No.10, Attachment G
27	MECHANICAL-PERFORMANCE/DURABILITY/ SAFETY TEST	Natural Rubber Latex Male Condoms	Freedom from Holes	RDC NO.554, Annex VII

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28	MECHANICAL-PERFORMANCE/DURABILITY/ SAFETY TEST	Natural Rubber Latex Male Condoms	Freedom from Holes	Schedule - R of Drugs & Cosmetic Rules, Paragraph 10
29	MECHANICAL-PERFORMANCE/DURABILITY/ SAFETY TEST	Natural Rubber Latex Male Condoms	Length	ASTM D3492, Annex A1
30	MECHANICAL-PERFORMANCE/DURABILITY/ SAFETY TEST	Natural Rubber Latex Male Condoms	Length	ISO 4074, Annex D
31	MECHANICAL-PERFORMANCE/DURABILITY/ SAFETY TEST	Natural Rubber Latex Male Condoms	Length	MERCOSUR/GMC/RES.No.10, Attachment B
32	MECHANICAL-PERFORMANCE/DURABILITY/ SAFETY TEST	Natural Rubber Latex Male Condoms	Length	RDC NO.554, Annex II
33	MECHANICAL-PERFORMANCE/DURABILITY/ SAFETY TEST	Natural Rubber Latex Male Condoms	Length	Schedule - R of Drugs & Cosmetic Rules, Paragraph 8, Point No. 1
34	MECHANICAL-PERFORMANCE/DURABILITY/ SAFETY TEST	Natural Rubber Latex Male Condoms	Lubricant Quantity	ISO 4074, Annex C
35	MECHANICAL-PERFORMANCE/DURABILITY/ SAFETY TEST	Natural Rubber Latex Male Condoms	Lubricant Quantity	Schedule - R of Drugs & Cosmetic Rules, Paragraph 11
36	MECHANICAL-PERFORMANCE/DURABILITY/ SAFETY TEST	Natural Rubber Latex Male Condoms	Package Integrity of Individual Containers	ISO 4074, Annex N
37	MECHANICAL-PERFORMANCE/DURABILITY/ SAFETY TEST	Natural Rubber Latex Male Condoms	Package Integrity of Individual Containers	MERCOSUR/GMC/RES. No. 10, Attachment H
38	MECHANICAL-PERFORMANCE/DURABILITY/ SAFETY TEST	Natural Rubber Latex Male Condoms	Package Integrity of Individual Containers	RDC NO. 554, Annex VIII
39	MECHANICAL-PERFORMANCE/DURABILITY/ SAFETY TEST	Natural Rubber Latex Male Condoms	Packaging and Labelling	ASTM D3492, Section 6
40	MECHANICAL-PERFORMANCE/DURABILITY/ SAFETY TEST	Natural Rubber Latex Male Condoms	Packaging and Labelling	ISO 4074, Clause 15
41	MECHANICAL-PERFORMANCE/DURABILITY/ SAFETY TEST	Natural Rubber Latex Male Condoms	Packaging and Labelling	MERCOSUR/GMC/RES. No. 10, Attachment I

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42	MECHANICAL-PERFORMANCE/DURABILITY/ SAFETY TEST	Natural Rubber Latex Male Condoms	Packaging and Labelling	RDC NO. 554, Section II & III
43	MECHANICAL-PERFORMANCE/DURABILITY/ SAFETY TEST	Natural Rubber Latex Male Condoms	Packaging and Labelling	Schedule - R of Drugs & Cosmetic Rules, Paragraph 13
44	MECHANICAL-PERFORMANCE/DURABILITY/ SAFETY TEST	Natural Rubber Latex Male Condoms	Tensile Strength	ISO 4074, Annex J
45	MECHANICAL-PERFORMANCE/DURABILITY/ SAFETY TEST	Natural Rubber Latex Male Condoms	Thickness	ASTM D3492, Section 4.2
46	MECHANICAL-PERFORMANCE/DURABILITY/ SAFETY TEST	Natural Rubber Latex Male Condoms	Thickness	ISO 4074, Annex F
47	MECHANICAL-PERFORMANCE/DURABILITY/ SAFETY TEST	Natural Rubber Latex Male Condoms	Thickness	MERCOSUR/GMC/RES. No. 10, Attachment D
48	MECHANICAL-PERFORMANCE/DURABILITY/ SAFETY TEST	Natural Rubber Latex Male Condoms	Thickness	RDC NO. 554, Annex IV
49	MECHANICAL-PERFORMANCE/DURABILITY/ SAFETY TEST	Natural Rubber Latex Male Condoms	Thickness	Schedule - R of Drugs & Cosmetic Rules, Paragraph 8, Point No. 3
50	MECHANICAL-PERFORMANCE/DURABILITY/ SAFETY TEST	Natural Rubber Latex Male Condoms	Width	ASTM D3492, Section 4.2
51	MECHANICAL-PERFORMANCE/DURABILITY/ SAFETY TEST	Natural Rubber Latex Male Condoms	Width	ISO 4074, Annex E
52	MECHANICAL-PERFORMANCE/DURABILITY/ SAFETY TEST	Natural Rubber Latex Male Condoms	Width	MERCOSUR/GMC/RES. No. 10, Attachment C
53	MECHANICAL-PERFORMANCE/DURABILITY/ SAFETY TEST	Natural Rubber Latex Male Condoms	Width	RDC NO. 554, Annex III
54	MECHANICAL-PERFORMANCE/DURABILITY/ SAFETY TEST	Natural Rubber Latex Male Condoms	Width	Schedule - R of Drugs & Cosmetic Rules, Paragraph 8, Point No. 2
55	MECHANICAL-PERFORMANCE/DURABILITY/ SAFETY TEST	Synthetic Polyisoprene Male Condoms	Burst Pressure - Untreated Condoms	ISO 23409, Annex H

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56	MECHANICAL-PERFORMANCE/DURABILITY/ SAFETY TEST	Synthetic Polyisoprene Male Condoms	Burst Volume - Untreated Condoms	ISO 23409, Annex H
57	MECHANICAL-PERFORMANCE/DURABILITY/ SAFETY TEST	Synthetic Polyisoprene Male Condoms	Freedom from Holes	ISO 23409, Annex J
58	MECHANICAL-PERFORMANCE/DURABILITY/ SAFETY TEST	Synthetic Polyisoprene Male Condoms	Length	ISO 23409, Annex D
59	MECHANICAL-PERFORMANCE/DURABILITY/ SAFETY TEST	Synthetic Polyisoprene Male Condoms	Lubricant Quantity	ISO 23409, Annex C
60	MECHANICAL-PERFORMANCE/DURABILITY/ SAFETY TEST	Synthetic Polyisoprene Male Condoms	Package Integrity of Individual Containers	ISO 23409, Annex M
61	MECHANICAL-PERFORMANCE/DURABILITY/ SAFETY TEST	Synthetic Polyisoprene Male Condoms	Packaging and Labelling	ISO 23409,Clause 16
62	MECHANICAL-PERFORMANCE/DURABILITY/ SAFETY TEST	Synthetic Polyisoprene Male Condoms	Thickness	ISO 23409, Annex F
63	MECHANICAL-PERFORMANCE/DURABILITY/ SAFETY TEST	Synthetic Polyisoprene Male Condoms	Width	ISO 23409, Annex E