

Quality And Accreditation Institute

Centre for International Accreditation



Certificate of Accreditation

Dhanajeevam Labs Private Limited

334 F, Sundarapuram road, Madukkarai market,
Coimbatore Tamil Nadu, 641105, India

has been assessed and accredited in accordance with the Standard

ISO/IEC 17025:2017

“General Requirements for the Competence of Testing and Calibration Laboratories”

In the field of

Testing

*This certificate remains valid for the Scope of Accreditation as specified in
the annexure subject to continued compliance with the above standard &
any other requirements specified by QAI.*



QAI/CIA/TL/2026/0187

Valid from: 26 August 2026

Valid until: 25 August 2028

Dr. Bhupendra Kumar Rana
Chief Executive Officer

Prof. Vikram Kumar
Chair, CIA



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Accreditation Standard: ISO/IEC 17025:2017

Mechanical Testing			
Sl. No.	Product(s)/Material of Test	Specific Tests Performed	Test Method
	Medical devices		
1.	Non-wovens - Medical textiles, Surgical gowns, Drapes, Kits, Non- woven fabrics- Natural product coated, Chemical coated, non- coated	Elongation at break cross machine direction	IS 15891-3 :2011
2.	Non-wovens - Medical textiles, Surgical gowns, Drapes, Kits, Non- woven fabrics- Natural product coated, Chemical coated, non- coated	Elongation at Break- cross machine direction	ISO9073-3: 2023
3.	Non-wovens - Medical textiles, Surgical gowns, Drapes, Kits, Non- woven fabrics- Natural product coated, Chemical coated, non- coated	Elongation at Break- Machine Direction	IS 15891Part 3:2011
4.	Non-wovens - Medical textiles, Surgical gowns, Drapes, Kits, Non-wovens - Medical textiles, Surgical gowns, Drapes, Kits, Non- woven fabrics- Natural product coated, Chemical coated, non-coated,	Elongation at break- Machine direction	ISO 9073-3:2023
5.	Non-wovens - Medical textiles, Surgical gowns, Drapes, Kits, Non- woven fabrics- Natural product coated, Chemical coated, non- coated,	Force at break cross machine direction	IS 15891-3 :2011

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	Medical devices		
6.	Non-wovens - Medical textiles, Surgical gowns, Drapes, Kits, Non- woven fabrics- Natural product coated, Chemical coated, non- coated	Force at Break- cross machine direction	ISO 9073-3: 2023
7.	Non-wovens - Medical textiles, Surgical gowns, Drapes, Kits, Non- woven fabrics- Natural product coated, Chemical coated, non- coated,	Force at break machine direction	IS 15891-3 :2011
8.	Non-wovens - Medical textiles, Surgical gowns, Drapes, Kits, Non- woven fabrics- Natural product coated, Chemical coated, non- coated	Force at Break- machine direction	ISO 9073-3: 2023
9.	Non-wovens - Medical textiles, Surgical gowns, Drapes, Kits, Non- woven fabrics- Natural product coated, Chemical coated, non- coated	Mass per unit area	IS 15891 -1:2011
10.	Non-wovens - Medical textiles, Surgical gowns, Drapes, Kits, Non- woven fabrics- Natural product coated, Chemical coated, non- coated	Mass per unit area	ISO 15891-1:2023
11.	Non-wovens - Medical textiles, Surgical gowns, Drapes, Kits, Non- woven fabrics- Natural product coated, Chemical coated, non- coated	Thickness	IS 15891 -2:2011

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	Medical devices		
12.	Non-wovens - Medical textiles, Surgical gowns, Drapes, Kits, Non- woven fabrics- Natural product coated, Chemical coated, non- coated	Thickness	ISO 9073-2:1995
13.	Medical device Packaging materials	Determination of integrity of seals by visual inspection	ASTM F 1886/1886M-2024
14.	Medical device Packaging materials	Determination of Leaks by bubble emission	ASTM D3078- 02
15.	Medical device Packaging materials	Detecting seal leaks by dye penetration	ASTM F 1929-12
16.	Medical device Packaging materials	Seal strength	ASTM F88/F88M-21
17.	Medical device Packaging materials	Non-destructive detection of Leaks by vacuum decay method	ASTM F2338-24
18.	Medical device Packaging materials	Detecting gross leaks in packaging by internal Pressurization	ASTM F2096-11(2019)
19.	Medical device Packaging materials	Seal width/Peelability	EN 868-5:2018 Annexure E
20.	Medical device packaging materials	Accelerated ageing	ASTM F1980-21
21.	Packaging for terminally sterilized medical devices	Packaging material validation	ISO 11607-1:2019
22.	Packaging for terminally sterilized medical devices	Packaging material validation	ISO 11607-2:2019

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Sl. No.	Product(s)/Material of Test	Specific Tests Performed	Test Method
	Medical devices		
23.	Rubber and Rubber products	Standard Test Methods for Vulcanized Rubber and Thermoplastic Elastomers— Tension	ASTM D412-16(2021)
24.	Rubber and Rubber products	Rubber vulcanized or thermoplastic-Determination of tensile stress-strain properties	ISO 37:2017
25.	Intraocular lens	Sample Preparation Photostability	ISO 11979-5:2020
26.	Intraocular lens	Sample preparation Nd- YAG laser exposure test	ISO 11979-5:2020
27.	Absorbent cotton gauze, absorbent cotton, viscose gauze	Fibre Identification	EN 14079:2003Clause 5.2
28.	Absorbent cotton gauze, absorbent cotton, viscose gauze	Acidity/ Alkalinity	EN 14079:2003Clause 5.3
29.	Absorbent cotton gauze, absorbent cotton, viscose gauze	foreign fibres	EN 14079:2003Clause 5.4
30.	Absorbent cotton gauze, absorbent cotton, viscose gauze	Thread count (warp)	EN 14079:2003Clause 5.6

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Mechanical Testing			
Sl. No.	Product(s)/Material of Test	Specific Tests Performed	Test Method
	Medical devices		
31.	Absorbent cotton gauze, absorbent cotton, viscose gauze	Thread count (weft)	EN 14079:2003 Clause 5.6
32.	Absorbent cotton gauze, absorbent cotton, viscose gauze	Mass per Square meter	EN 14079:2003 Clause 5.7
33.	Absorbent cotton gauze, absorbent cotton, viscose gauze	Minimum breaking load(warp)	EN 14079:2003 Clause 5.8
34.	Absorbent cotton gauze, absorbent cotton, viscose gauze	Minimum breaking load (weft)	EN 14079:2003 Clause 5.8
35.	Absorbent cotton gauze, absorbent cotton, viscose gauze	Sinking time	EN 14079:2003 Clause 5.9
36.	Absorbent cotton gauze, absorbent cotton, viscose gauze	Surface active substances	EN 14079:2003 Clause 5.11
37.	Absorbent cotton gauze, absorbent cotton, viscose gauze	Water soluble substances	EN 14079:2003 Clause 5.12
38.	Absorbent cotton gauze, absorbent cotton, viscose gauze	Loss on drying	EN 14079:2003 Clause 5.15
39.	Absorbent cotton gauze, absorbent cotton, viscose gauze	Starch/Dextrin	EN 14079:2003 Clause 5.13



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Mechanical Testing			
Sl. No.	Product(s)/Material of Test	Specific Tests Performed	Test Method
	Medical devices		
40.	Absorbent cotton gauze, absorbent cotton, viscose gauze	Coloring matter	EN 14079:2003 Annexure A
41.	Absorbent cotton gauze, absorbent cotton, viscose gauze	Ether soluble substances	EN 14079:2003 Clause 5.10
42.	Critical and semi critical medical devices and raw material, semi- finished material used for manufacturing medical devices (Reusable)	Processing of health care products: Information to be provided for the processing of medical device	ISO 17664-1; 2021
43.	Non critical medical devices and raw material, semi-finished material used for manufacturing medical devices (Reusable)	Processing of health care products: Information to be provided for the processing of medical device; Non critical medical devices	ISO 17664-2; 2023
44.	Medical devices and raw material, semi-finished material used for manufacturing medical devices (Reusable)	Requirements for development and validation of cleaning process for medical devices	ANSI/AAMI ST98 2021



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Biological Testing			
Sl. No.	Product(s)/Material of Test	Specific Tests Performed	Test Method
	Medical Accessories & Surgical products		
1.	Biological Indicators	Sterilization- Biological Indicator Validation	ISO 11138-1:2017
2.	Biological Indicators	Sterilization- Biological Indicators for ethylene oxide sterilization process	ISO 11138-2:2017
3.	Chemical Indicators	Sterilization- Chemical Indicator validation	ISO 11140-1:2014
4.	Chemical Indicators	Sterilization- Test Equipment and methods	ISO 11140-2:1998
5.	Chemical Indicators	Class 2 indicator systems for use in the Bowie and Dick- type steam penetration test	ISO 11140-3:2007
6.	Chemical Indicators	Class 2 indicators as an alternative to the Bowie and Dick type test for detection of steam penetration	ISO 11140-4:2007
7.	Chemical Indicators	Class 2 indicators for Bowie and Dick-type air removal tests	ISO 11140-5:2007
8.	Medical devices and raw material, semi-finished material used for manufacturing medical devices	Moist Heat – Requirements for the development, validation, and routine control of a sterilization process for medical devices	ISO 17665:2024



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Sl. No.	Product(s)/Material of Test	Specific Tests Performed	Test Method
	Medical Accessories & Surgical products		
9.	Medical devices and raw material, semi-finished material used for manufacturing medical devices	Biological Evaluation; Sample Preparation for Chemical characterization of medical device materials within a risk management process	ISO 10993-18:2020/Amd:2022
10.	Medical devices and raw material, semi-finished material used for manufacturing medical devices	Biological Evaluation; Toxicological risk assessment of medical device constituents	ISO 10993-17:2023
11.	Breathing gas pathways and accessories	Sample preparation for emissions of particulate matter	ISO 18562-2:2024
12.	Breathing gas pathways and accessories	Sample preparation emissions of volatile organic substances	ISO 18562-3:2024
13.	Breathing gas pathways and accessories	Sample preparation for leachable in condensate	ISO 18562-4:2024
14.	Intraocular lens	Sample preparation for Exhaustive extraction test	ISO 11979-5:2020
15.	Intraocular lens	Sample preparation for leachable	ISO 11979-5:2020
16.	Intraocular lens	Sample preparation for Hydrolytic stability	ISO 11979-5:2020
17.	Injections, Parenteral infusions, Cardioplegia delivery system	Microscopic Particle count	USP <788>:2026

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