

Quality And Accreditation Institute

Centre for International Accreditation



Certificate of Accreditation

Chemzin Biotox Research Institute Private Limited

1st Floor, Plot no-94, EPIP Industrial Area, Phase 1, Jharmajri, Baddi
Solan-174103, Himachal Pradesh, 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/2026/0188

Valid from: 26 August 2026

Dr. Bhupendra Kumar Rana
Chief Executive Officer

Valid until: 25 August 2028

Prof. Vikram Kumar
Chair, CIA



Quality And Accreditation Institute

Centre for Laboratory Accreditation



Scope of Accreditation

Chemzin Biotox Research Institute Private Limited

1st Floor, Plot no-94, EPIP Ind. Area Phase-1, Jharmajri, Baddi

Solan-174103, Himachal Pradesh, India

QAI/CIA/TL/2026/0188

Valid from: 26 August 2026

Valid until: 25 August 2028

Accreditation Standard: ISO/IEC 17025:2017

Chemical Testing			
Sl. No.	Product(s)/Material of Test	Specific Tests Performed	Test Method
	Drugs & Pharmaceuticals		
1.	Enoxaparine Sodium Injection	Anti-factor Xa	Indian Pharmacopoeia 2022 (Volume 02, Page 2234 to 2236) British Pharmacopoeia (BP 2025 (Ph. Eur. 11.6 update))
2.	Enoxaparine Sodium Injection	Anti-factor IIa	Indian Pharmacopoeia 2022 (Volume 02, Page 2234 to 2236) British Pharmacopoeia (BP 2025 (Ph. Eur. 11.6 update))
3.	Heparin Sodium	Anti-factor Xa	Indian Pharmacopoeia 2022 (Volume 02, Page 2512 to 2517) British Pharmacopoeia (BP 2025 (Ph. Eur. 11.6 update))
4.	Heparin Sodium	Anti-factor IIa	Indian Pharmacopoeia 2022 (Volume 02, Page 2512 to 2517) British Pharmacopoeia (BP 2025 (Ph. Eur. 11.6 update))
5.	Heparin Sodium Injection	Anti-factor Xa	Indian Pharmacopoeia 2022 (Volume 02, Page 2234 to 2236) British Pharmacopoeia (BP 2025 (Ph. Eur. 11.6 update))
6.	Heparin Sodium Injection	Anti-factor IIa	Indian Pharmacopoeia 2022 (Volume 02, Page 2234 to 2236) British Pharmacopoeia (BP 2025 (Ph. Eur. 11.6 update))



Quality And Accreditation Institute

Centre for Laboratory Accreditation



Scope of Accreditation

Chemzin Biotox Research Institute Private Limited

1st Floor, Plot no-94, EPIP Ind. Area Phase-1, Jharmajri, Baddi

Solan-174103, Himachal Pradesh, India

QAI/CIA/TL/2026/0188

Valid from: 26 August 2026

Valid until: 25 August 2028

Accreditation Standard: ISO/IEC 17025:2017

Biological Testing			
Sl. No.	Product(s)/Material of Test	Specific Tests Performed	Test Method
	Medical Accessories & Surgical Products		
1.	Insulin Pen Needles	Cytotoxicity (MEM)	ISO 10993-5:2009
2.	Insulin Pen Needles	Skin irritation	ISO 10993-23:2020/IS 17932: PART 7: 2024
3.	Insulin Pen Needles	Guinea pig maximization / skin sensitization	ISO 10993-10:2021/IS 17932: PART 6: 2023
4.	Insulin Pen Needles	Pyrogen Test- Material Mediated Pyrogenicity	ISO 10993-11:2017 (Annexure G)
5.	Insulin Pen Needles	Hemocompatibility	ISO 10993-4:2017
6.	Insulin Pen Needles	Genotoxicity- Direct	ISO 10993-3:2014
7.	Insulin Pen Needles	Acute Systemic /Sub-Acute Systemic /Chronic/ Sub-Chronic Toxicity	ISO 10993-11:2017
8.	Positioner for CABG	Skin irritation	ISO 10993-23:2020/IS 17932: PART 7: 2024
9.	Positioner for CABG	Guinea pig maximization / skin sensitization	ISO 10993-10:2021/IS 17932: PART 6: 2023
10.	Positioner for CABG	Pyrogen Test- Material Mediated Pyrogenicity	ISO 10993-11:2017 (Annexure G)
11.	Blood Separating bottles	Cytotoxicity (MEM)	ISO 10993-5:2009
12.	Blood Separating bottles	Skin irritation	ISO 10993-23:2020/IS 17932: PART 7: 2024



Quality And Accreditation Institute

Centre for Laboratory Accreditation



Scope of Accreditation

Chemzin Biotox Research Institute Private Limited

1st Floor, Plot no-94, EPIP Ind. Area Phase-1, Jharmajri, Baddi

Solan-174103, Himachal Pradesh, India

QAI/CIA/TL/2026/0188

Valid from: 26 August 2026

Valid until: 25 August 2028

Accreditation Standard: ISO/IEC 17025:2017

Biological Testing			
Sl. No.	Product(s)/Material of Test	Specific Tests Performed	Test Method
	Medical Accessories & Surgical Products		
13.	Blood Separating bottles	Guinea pig maximization / skin sensitization	ISO 10993-10:2021/IS 17932: PART 6: 2023
14.	Blood Separating bottles	Pyrogen Test- Material Mediated Pyrogenicity	ISO 10993-11:2017 (Annexure G)
15.	Blood Separating bottles	Hemocompatibility	ISO 10993-4:2017
16.	Blood Separating bottles	Genotoxicity- Direct	ISO 10993-3:2014
17.	Blood Separating bottles	Acute Systemic /Sub-Acute Systemic /Chronic/ Sub-Chronic Toxicity	ISO 10993-11:2017
18.	Bone Implants	Cytotoxicity (MEM)	ISO 10993-5:2009
19.	Bone Implants	Skin irritation	ISO 10993-23:2020/IS 17932: PART 7: 2024
20.	Bone Implants	Guinea pig maximization / skin sensitization	ISO 10993-10:2021/IS 17932: PART 6: 2023
21.	Bone Implants	Pyrogen Test- Material Mediated Pyrogenicity	ISO 10993-11:2017 (Annexure G)
22.	Bone Implants	Hemocompatibility	ISO 10993-4:2017
23.	Bone Implants	Genotoxicity- Direct	ISO 10993-3:2014
24.	Bone Implants	Acute Systemic /Sub-Acute Systemic /Chronic/ Sub-Chronic Toxicity	ISO 10993-11:2017



Quality And Accreditation Institute

Centre for Laboratory Accreditation



Scope of Accreditation

Chemzin Biotox Research Institute Private Limited

1st Floor, Plot no-94, EPIP Ind. Area Phase-1, Jharmajri, Baddi

Solan-174103, Himachal Pradesh, India

QAI/CIA/TL/2026/0188

Valid from: 26 August 2026

Valid until: 25 August 2028

Accreditation Standard: ISO/IEC 17025:2017

Biological Testing			
Sl. No.	Product(s)/Material of Test	Specific Tests Performed	Test Method
	Medical Accessories & Surgical Products		
25.	Bone Implants	Skin irritation	ISO 10993-23:2020/IS 17932: PART 7: 2024
26.	Bone Implants	Guinea pig maximization / skin sensitization	ISO 10993-10:2021/IS 17932: PART 6: 2023
27.	Bone Implants	Pyrogen Test- Material Mediated Pyrogenicity	ISO 10993-11:2017 (Annexure G)
28.	Bone Implants	Implantation	ISO-10993-6
29.	Orthopaedic screws	Skin irritation	ISO 10993-23:2020/IS 17932: PART 7: 2024
30.	Orthopaedic screws	Guinea pig maximization / skin sensitization	ISO 10993-10:2021/IS 17932: PART 6: 2023
31.	Orthopaedic screws	Pyrogen Test- Material Mediated Pyrogenicity	ISO 10993-11:2017 (Annexure G)
32.	Orthopaedic screws	Hemocompatibility	ISO 10993-4:2017
33.	Orthopaedic screws	Genotoxicity	ISO 10993-3:2014
34.	Orthopaedic screws	Acute Systemic /Sub-Acute Systemic /Chronic/ Sub-Chronic Toxicity	ISO 10993-11:2017
35.	Orthopaedic screws	Implantation	ISO-10993-6
36.	Orthopaedic screws	Sub-chronic toxicity (90 days, 13 weeks)	ISO 10993-11:2017



Quality And Accreditation Institute

Centre for Laboratory Accreditation



Scope of Accreditation

Chemzin Biotox Research Institute Private Limited

1st Floor, Plot no-94, EPIP Ind. Area Phase-1, Jharmajri, Baddi

Solan-174103, Himachal Pradesh, India

QAI/CIA/TL/2026/0188

Valid from: 26 August 2026

Valid until: 25 August 2028

Accreditation Standard: ISO/IEC 17025:2017

Biological Testing			
Sl. No.	Product(s)/Material of Test	Specific Tests Performed	Test Method
	Medical Accessories & Surgical Products		
37.	Orthopaedic prosthesis	Skin irritation	ISO 10993-23:2020/IS 17932: PART 7 : 2024
38.	Orthopaedic prosthesis	Guinea pig maximization / skin sensitization	ISO 10993-10:2021/IS 17932: PART 6 : 2023
39.	Orthopaedic prosthesis	Pyrogen Test- Material Mediated Pyrogenicity	ISO 10993-11:2017 (Annexure G)
40.	Orthopaedic prosthesis	Hemocompatibility	ISO 10993-4:2017
41.	Orthopaedic prosthesis	Genotoxicity- Direct	ISO 10993-3:2014
42.	Orthopaedic prosthesis	Acute Systemic /Sub-Acute Systemic /Chronic/ Sub-Chronic Toxicity	ISO 10993-11:2017
43.	Orthopaedic prosthesis	Implantation	ISO-10993-6
44.	Orthopaedic prosthesis	Sub-chronic toxicity (90 days, 13 weeks)	ISO 10993-11:2017
45.	Orthopaedic pins	Skin irritation	ISO 10993-23:2020/IS 17932: PART 7: 2024
46.	Orthopaedic pins	Guinea pig maximization / skin sensitization	ISO 10993-10:2021/IS 17932: PART 6: 2023
47.	Orthopaedic pins	Pyrogen Test- Material Mediated Pyrogenicity	ISO 10993-11:2017 (Annexure G)
48.	Orthopaedic pins	Hemocompatibility	ISO 10993-4:2017
49.	Orthopaedic pins	Genotoxicity	ISO 10993-3:2014



Quality And Accreditation Institute

Centre for Laboratory Accreditation



Scope of Accreditation

Chemzin Biotox Research Institute Private Limited

1st Floor, Plot no-94, EPIP Ind. Area Phase-1, Jharmajri, Baddi

Solan-174103, Himachal Pradesh, India

QAI/CIA/TL/2026/0188

Valid from: 26 August 2026

Valid until: 25 August 2028

Accreditation Standard: ISO/IEC 17025:2017

Biological Testing			
Sl. No.	Product(s)/Material of Test	Specific Tests Performed	Test Method
	Medical Accessories & Surgical Products		
50.	Orthopaedic pins	Acute Systemic /Sub-Acute Systemic /Chronic/ Sub-Chronic Toxicity	ISO 10993-11:2017
51.	Orthopaedic pins	Implantation	ISO-10993-6
52.	Orthopaedic Plates	Sub-chronic toxicity (90 days, 13 weeks)	ISO 10993-11:2017
53.	Orthopaedic Plates	Skin irritation	ISO 10993-23:2020/IS 17932: PART 7: 2024
54.	Orthopaedic Plates	Guinea pig maximization / skin sensitization	ISO 10993-10:2021/IS 17932: PART 6: 2023
55.	Orthopaedic Plates	Pyrogen Test- Material Mediated Pyrogenicity	ISO 10993-11:2017 (Annexure G)
56.	Orthopaedic Plates	Hemocompatibility	ISO 10993-4:2017
57.	Orthopaedic Plates	Genotoxicity- Direct	ISO 10993-3:2014
58.	Orthopaedic Plates	Acute Systemic /Sub-Acute Systemic /Chronic/ Sub-Chronic Toxicity	ISO 10993-11:2017
59.	Orthopaedic Plates	Implantation	ISO-10993-6
60.	Orthopaedic Plates	Sub-chronic toxicity (90 days, 13 weeks)	ISO 10993-11:2017
61.	Orthopaedic wires	Skin irritation	ISO 10993-23:2020/IS 17932: PART 7: 2024



Quality And Accreditation Institute

Centre for Laboratory Accreditation



Scope of Accreditation

Chemzin Biotox Research Institute Private Limited

1st Floor, Plot no-94, EPIP Ind. Area Phase-1, Jharmajri, Baddi

Solan-174103, Himachal Pradesh, India

QAI/CIA/TL/2026/0188

Valid from: 26 August 2026

Valid until: 25 August 2028

Accreditation Standard: ISO/IEC 17025:2017

Biological Testing			
Sl. No.	Product(s)/Material of Test	Specific Tests Performed	Test Method
	Medical Accessories & Surgical Products		
62.	Orthopaedic wires	Guinea pig maximization / skin sensitization	ISO 10993-10:2021/IS 17932: PART 6: 2023
63.	Orthopaedic wires	Pyrogen Test- Material Mediated Pyrogenicity	ISO 10993-11:2017 (Annexure G)
64.	Orthopaedic wires	Hemocompatibility	ISO 10993-4:2017
65.	Orthopaedic wires	Genotoxicity- Direct	ISO 10993-3:2014
66.	Orthopaedic wires	Acute Systemic /Sub-Acute Systemic /Chronic/ Sub-Chronic Toxicity	ISO 10993-11:2017
67.	Orthopaedic wires	Implantation	ISO-10993-6
68.	Orthopaedic wires	Sub-chronic toxicity (90 days, 13 weeks)	ISO 10993-11:2017
69.	Rubber Stoppers	Skin irritation	ISO 10993-23:2020/IS 17932: PART 7: 2024
70.	Rubber Stoppers	Guinea pig maximization / skin sensitization	ISO 10993-10:2021/IS 17932: PART 6: 2023
71.	Rubber Stoppers	Pyrogen Test- Material Mediated Pyrogenicity	ISO 10993-11:2017 (Annexure G)
72.	Rubber Stoppers	Hemocompatibility	ISO 10993-4:2017
73.	Rubber Stoppers	Genotoxicity- Direct	ISO 10993-3:2014



Quality And Accreditation Institute

Centre for Laboratory Accreditation



Scope of Accreditation

Chemzin Biotox Research Institute Private Limited

1st Floor, Plot no-94, EPIP Ind. Area Phase-1, Jharmajri, Baddi

Solan-174103, Himachal Pradesh, India

QAI/CIA/TL/2026/0188

Valid from: 26 August 2026

Valid until: 25 August 2028

Accreditation Standard: ISO/IEC 17025:2017

Biological Testing			
Sl. No.	Product(s)/Material of Test	Specific Tests Performed	Test Method
	Medical Accessories & Surgical Products		
74.	Rubber Stoppers	Acute Systemic /Sub-Acute Systemic /Chronic/ Sub-Chronic Toxicity	ISO 10993-11:2017
75.	Ryles Tube	Skin irritation	ISO 10993-23:2020/IS 17932: PART 7: 2024
76.	Ryles Tube	Guinea pig maximization / skin sensitization	ISO 10993-10:2021/IS 17932: PART 6 : 2023
77.	Ryles Tube	Pyrogen Test- Material Mediated Pyrogenicity	ISO 10993-11:2017 (Annexure G)
78.	Ryles Tube	Hemocompatibility	ISO 10993-4:2017
79.	Ryles Tube	Genotoxicity- Direct	ISO 10993-3:2014
80.	Ryles Tube	Acute Systemic /Sub-Acute Systemic /Chronic/ Sub-Chronic Toxicity	ISO 10993-11:2017
81.	Mesh for Muscles	Skin irritation	ISO 10993-23:2020/IS 17932: PART 7: 2024
82.	Mesh for Muscles	Guinea pig maximization / skin sensitization	ISO 10993-10:2021/IS 17932: PART 6: 2023
83.	Mesh for Muscles	Pyrogen Test- Material Mediated Pyrogenicity	ISO 10993-11:2017 (Annexure G)
84.	Mesh for Muscles	Hemocompatibility	ISO 10993-4:2017
85.	Mesh for Muscles	Genotoxicity- Direct	ISO 10993-3:2014

This is annexure to 'Certificate of Accreditation' and does not require any signature.

www.qai.org.in



8 of 76

Quality And Accreditation Institute

Centre for Laboratory Accreditation



Scope of Accreditation

Chemzin Biotox Research Institute Private Limited

1st Floor, Plot no-94, EPIP Ind. Area Phase-1, Jharmajri, Baddi

Solan-174103, Himachal Pradesh, India

QAI/CIA/TL/2026/0188

Valid from: 26 August 2026

Valid until: 25 August 2028

Accreditation Standard: ISO/IEC 17025:2017

Biological Testing			
Sl. No.	Product(s)/Material of Test	Specific Tests Performed	Test Method
	Medical Accessories & Surgical Products		
86.	Mesh for Muscles	Acute Systemic /Sub-Acute Systemic /Chronic/ Sub-Chronic Toxicity	ISO 10993-11:2017
87.	Mesh for Muscles	Implantation	ISO-10993-6
88.	Mesh for Muscles	Sub-chronic toxicity (90 days, 13 weeks)	ISO 10993-11:2017
89.	Cannula	Guinea pig maximization / skin sensitization	ISO 10993-10:2021/IS 17932: PART 6: 2023
90.	Cannula	Pyrogen Test- Material Mediated Pyrogenicity	ISO 10993-11:2017 (Annexure G)
91.	Cannula	Hemocompatibility	ISO 10993-4:2017
92.	Cannula	Genotoxicity- Direct	ISO 10993-3:2014
93.	Cannula	Acute Systemic /Sub-Acute Systemic /Chronic/ Sub-Chronic Toxicity	ISO 10993-11:2017
94.	Sutures	Skin irritation	ISO 10993-23:2020/IS 17932: PART 7: 2024
95.	Sutures	Guinea pig maximization / skin sensitization	ISO 10993-10:2021/IS 17932: PART 6: 2023
96.	Sutures	Pyrogen Test- Material Mediated Pyrogenicity	ISO 10993-11:2017 (Annexure G)
97.	Sutures	Hemocompatibility	ISO 10993-4:2017



Quality And Accreditation Institute

Centre for Laboratory Accreditation



Scope of Accreditation

Chemzin Biotox Research Institute Private Limited

1st Floor, Plot no-94, EPIP Ind. Area Phase-1, Jharmajri, Baddi

Solan-174103, Himachal Pradesh, India

QAI/CIA/TL/2026/0188

Valid from: 26 August 2026

Valid until: 25 August 2028

Accreditation Standard: ISO/IEC 17025:2017

Biological Testing			
Sl. No.	Product(s)/Material of Test	Specific Tests Performed	Test Method
	Medical Accessories & Surgical Products		
98.	Sutures	Genotoxicity- Direct	ISO 10993-3:2014
99.	Sutures	Implantation	ISO 10993-06:2026
100.	Sutures	Acute Systemic /Sub-Acute Systemic /Chronic/ Sub-Chronic Toxicity	ISO 10993-11:2017
101.	Catheter	Skin irritation	ISO 10993-23:2020/IS 17932: PART 7: 2024
102.	Catheter	Guinea pig maximization / skin sensitization	ISO 10993-10:2021/IS 17932: PART 6: 2023
103.	Catheter	Pyrogen Test- Material Mediated Pyrogenicity	ISO 10993-11:2017 (Annexure G)
104.	Catheter	Hemocompatibility	ISO 10993-4:2017
105.	Catheter	Genotoxicity- Direct	ISO 10993-3:2014
106.	Catheter	Acute Systemic /Sub-Acute Systemic /Chronic/ Sub-Chronic Toxicity	ISO 10993-11:2017
107.	Fat Binder tablets	Cytotoxicity (MEM)	ISO 10993-5:2009
108.	Fat Binder tablets	Skin irritation	ISO 10993-23:2020/IS 17932: PART 7: 2024
109.	Fat Binder tablets	Guinea pig maximization / skin sensitization	ISO 10993-10:2021/IS 17932: PART 6: 2023



Quality And Accreditation Institute

Centre for Laboratory Accreditation



Scope of Accreditation

Chemzin Biotox Research Institute Private Limited

1st Floor, Plot no-94, EPIP Ind. Area Phase-1, Jharmajri, Baddi

Solan-174103, Himachal Pradesh, India

QAI/CIA/TL/2026/0188

Valid from: 26 August 2026

Valid until: 25 August 2028

Accreditation Standard: ISO/IEC 17025:2017

Biological Testing			
Sl. No.	Product(s)/Material of Test	Specific Tests Performed	Test Method
	Medical Accessories & Surgical Products		
110.	Fat Binder tablets	Acute Systemic /Sub-Acute Systemic /Chronic/ Sub-Chronic Toxicity	ISO 10993-10:2021/IS 17932: PART 6: 2023
111.	Fat Binder tablets	Sub-Acute Systemic /Sub-Acute Systemic /Chronic/ Sub-Chronic Toxicity	ISO 10993-11:2017
112.	Fat Binder tablets	Sub-chronic toxicity (90 days, 13 weeks)	ISO 10993-11:2017
113.	Throat lozenges	Cytotoxicity (MEM)	ISO 10993-5:2009
114.	Throat lozenges	Acute Systemic /Sub-Acute Systemic /Chronic/ Sub-Chronic Toxicity	ISO 10993-11:2017
115.	Throat lozenges	Skin irritation	ISO 10993-23:2020/IS 17932: PART 7: 2024
116.	Throat lozenges	Guinea pig maximization / skin sensitization	ISO 10993-10:2021/IS 17932: PART 6: 2023
117.	Throat lozenges	Sub-chronic toxicity (90 days, 13 weeks)	ISO 10993-11:2017
118.	Nasal Gel for prevention of Epistaxis	Skin irritation	ISO 10993-23:2020/IS 17932: PART 7: 2024
119.	Nasal Gel for prevention of Epistaxis	Guinea pig maximization / skin sensitization	ISO 10993-10:2021/IS 17932: PART 6: 2023
120.	Nasal Gel for prevention of Epistaxis	Cytotoxicity (MEM)	ISO 10993-5:2009

This is annexure to 'Certificate of Accreditation' and does not require any signature.

www.qai.org.in



11 of 76

Quality And Accreditation Institute

Centre for Laboratory Accreditation



Scope of Accreditation

Chemzin Biotox Research Institute Private Limited

1st Floor, Plot no-94, EPIP Ind. Area Phase-1, Jharmajri, Baddi

Solan-174103, Himachal Pradesh, India

QAI/CIA/TL/2026/0188

Valid from: 26 August 2026

Valid until: 25 August 2028

Accreditation Standard: ISO/IEC 17025:2017

Biological Testing			
Sl. No.	Product(s)/Material of Test	Specific Tests Performed	Test Method
	Medical Accessories & Surgical Products		
121.	Nasal Gel for prevention of Epistaxis	Acute Systemic /Sub-Acute Systemic /Chronic/ Sub-Chronic Toxicity	ISO 10993-11:2017
122.	Nasal Gel for prevention of Epistaxis	Sub-chronic toxicity (90 days, 13 weeks)	ISO 10993-11:2017
123.	Nasal tube for sinus drainage	Guinea pig maximization / skin sensitization	ISO 10993-10:2021/IS 17932: PART 6: 2023
124.	Nasal tube for sinus drainage	Pyrogen Test- Material Mediated Pyrogenicity	ISO 10993-11:2017 (Annexure G)
125.	Nasal tube for sinus drainage	Hemocompatibility	ISO 10993-4:2017
126.	Nasal tube for sinus drainage	Genotoxicity- Direct	ISO 10993-3:2014
127.	Nasal tube for sinus drainage	Acute Systemic /Sub-Acute Systemic /Chronic/ Sub-Chronic Toxicity	ISO 10993-11:2017
128.	Nasal tube for sinus drainage	Cytotoxicity (MEM)	ISO 10993-5:2009
129.	Biopsy & Surgical Devices (Scalpels, Haemostat, Forceps, Needle Kit, Surgical Blades, Scissors, Suture)	Acute Systemic /Sub-Acute Systemic /Chronic/ Sub-Chronic Toxicity	ISO 10993-11:2017
130.	Biopsy & Surgical Devices (Scalpels, Haemostat, Forceps, Needle Kit, Surgical Blades, Scissors, Suture)	Cytotoxicity	ISO 10993-05:2009

This is annexure to 'Certificate of Accreditation' and does not require any signature.

www.qai.org.in



12 of 76

Quality And Accreditation Institute

Centre for Laboratory Accreditation



Scope of Accreditation

Chemzin Biotox Research Institute Private Limited

1st Floor, Plot no-94, EPIP Ind. Area Phase-1, Jharmajri, Baddi

Solan-174103, Himachal Pradesh, India

QAI/CIA/TL/2026/0188

Valid from: 26 August 2026

Valid until: 25 August 2028

Accreditation Standard: ISO/IEC 17025:2017

Biological Testing			
Sl. No.	Product(s)/Material of Test	Specific Tests Performed	Test Method
	Medical Accessories & Surgical Products		
131.	Biopsy & Surgical Devices (Scalpels, Hemostat, Forcep, Needle Kit, Surgical Blades, Scissors, Suture)	Hemocompatibility	ISO 10993-04:2017
132.	Biopsy & Surgical Devices (Scalpels, Hemostat, Forcep, Needle Kit, Surgical Blades, Scissors, Suture)	Genotoxicity	ISO 10993-03:2014
133.	Biopsy & Surgical Devices (Scalpels, Hemostat, Forcep, Needle Kit, Surgical Blades, Scissors, Suture)	Implantation	ISO 10993-06:2026
134.	Biopsy & Surgical Devices (Scalpels, Hemostat, Forcep, Needle Kit, Surgical Blades, Scissors, Suture)	Material Mediated Pyrogenicity	ISO 10993-11:2017 (Annexure G)
135.	Biopsy & Surgical Devices (Scalpels, Hemostat, Forcep, Needle Kit, Surgical Blades, Scissors, Suture)	Skin Sensitization Test	ISO 10993-10:2021/IS 17932: PART 6: 2023
136.	Biopsy & Surgical Devices (Scalpels, Hemostat, Forcep, Needle Kit, Surgical Blades, Scissors, Suture)	Test for Irritation	ISO 10993-23:2020/IS 17932: PART 7: 2023



Quality And Accreditation Institute

Centre for Laboratory Accreditation



Scope of Accreditation

Chemzin Biotox Research Institute Private Limited

1st Floor, Plot no-94, EPIP Ind. Area Phase-1, Jharmajri, Baddi

Solan-174103, Himachal Pradesh, India

QAI/CIA/TL/2026/0188

Valid from: 26 August 2026

Valid until: 25 August 2028

Accreditation Standard: ISO/IEC 17025:2017

Biological Testing			
Sl. No.	Product(s)/Material of Test	Specific Tests Performed	Test Method
	Medical Accessories & Surgical Products		
137.	Cannula (Coronary Artery, IV, IV with Safety Clip, Venous, Ventricular, Y Connector Arterial, Introducer Sheath)	Acute Systemic /Sub-Acute Systemic /Chronic/ Sub-Chronic Toxicity	ISO 10993-11:2017
138.	Cannula (Coronary Artery, IV, IV with Safety Clip, Venous, Ventricular, Y Connector Arterial, Introducer Sheath)	Cytotoxicity	ISO 10993-05:2009
139.	Cannula (Coronary Artery, IV, IV with Safety Clip, Venous, Ventricular, Y Connector Arterial, Introducer Sheath)	Hemocompatibility	ISO 10993-04:2017
140.	Cannula (Coronary Artery, IV, IV with Safety Clip, Venous, Ventricular, Y Connector Arterial, Introducer Sheath)	Genotoxicity	ISO 10993-03:2014
141.	Cannula (Coronary Artery, IV, IV with Safety Clip, Venous, Ventricular, Y Connector Arterial, Introducer Sheath)	Implantation	ISO 10993-06:2026
142.	Cannula (Coronary Artery, IV, IV with Safety Clip, Venous, Ventricular, Y Connector Arterial, Introducer Sheath)	Material Mediated Pyrogenicity	ISO 10993-11:2017 (Annexure G)



Quality And Accreditation Institute

Centre for Laboratory Accreditation



Scope of Accreditation

Chemzin Biotox Research Institute Private Limited

1st Floor, Plot no-94, EPIP Ind. Area Phase-1, Jharmajri, Baddi

Solan-174103, Himachal Pradesh, India

QAI/CIA/TL/2026/0188

Valid from: 26 August 2026

Valid until: 25 August 2028

Accreditation Standard: ISO/IEC 17025:2017

Biological Testing			
Sl. No.	Product(s)/Material of Test	Specific Tests Performed	Test Method
	Medical Accessories & Surgical Products		
143.	Cannula (Coronary Artery, IV, IV with Safety Clip, Venous, Ventricular, Y Connector Arterial, Introducer Sheath)	Skin Sensitization Test	ISO 10993-10:2021/IS 17932: PART 6: 2023
144.	Cannula (Coronary Artery, IV, IV with Safety Clip, Venous, Ventricular, Y Connector Arterial, Introducer Sheath)	Test for Irritation	ISO 10993-23:2020/IS 17932: PART 7: 2023
145.	Cardiovascular Devices (Temporary Pacemaker Electrodes, Heart Valves, vascular Grafts, Drug Eluting Bioresorbable cardiac stent system, Coronary Stent, Ureteral Stent, Heart Lung Pack)	Acute Systemic /Sub-Acute Systemic /Chronic/ Sub-Chronic Toxicity	ISO 10993-11:2017
146.	Cardiovascular Devices (Temporary Pacemaker Electrodes, Heart Valves, vascular Grafts, Drug Eluting Bioresorbable cardiac stent system, Coronary Stent, Ureteral Stent, Heart Lung Pack)	Cytotoxicity	ISO 10993-05:2009
147.		Hemocompatibility	ISO 10993-04:2017
148.		Genotoxicity	ISO 10993-03:2014
149.		Implantation Effects	ISO 10993-06:2026
150.		Material Mediated Pyrogenicity	ISO 10993-11:2017 (Annexure G)



Quality And Accreditation Institute

Centre for Laboratory Accreditation



Scope of Accreditation

Chemzin Biotox Research Institute Private Limited

1st Floor, Plot no-94, EPIP Ind. Area Phase-1, Jharmajri, Baddi

Solan-174103, Himachal Pradesh, India

QAI/CIA/TL/2026/0188

Valid from: 26 August 2026

Valid until: 25 August 2028

Accreditation Standard: ISO/IEC 17025:2017

Biological Testing			
Sl. No.	Product(s)/Material of Test	Specific Tests Performed	Test Method
	Medical Accessories & Surgical Products		
151.	Cardiovascular Devices (Temporary Pacemaker Electrodes, Heart Valves, vascular Grafts, Drug Eluting Bioresorbable cardiac stent system, Coronary Stent, Ureteral Stent, Heart Lung Pack)	Skin Sensitization Test	ISO 10993-10:2021/IS 17932: PART 6: 2023
152.		Test for Irritation	ISO 10993-23:2020/IS 17932: PART 7: 2023
153.	Catheters (Disposable Central Venous, Disposable Electrode Recording, Disposable Thermolulution, Double Lumen Set, Foley Two Way, Hemodialysis, Intravascular, Male, Multiple Lumen, Peritoneal Dialysis, Guide Wires, Urethral, Other Catheters, Double Lumen Hemodialysis Kit)	Acute Systemic /Sub-Acute Systemic /Chronic/ Sub-Chronic Toxicity	ISO 10993-11:2017
154.		Cytotoxicity	ISO 10993-05:2009
155.		Hemocompatibility	ISO 10993-04:2017
156.		Genotoxicity	ISO 10993-03:2014
157.		Implantation Effects	ISO 10993-06:2026
158.		Material Mediated Pyrogenicity	ISO 10993-11:2017 (Annexure G)
159.		Skin Sensitization Test	ISO 10993-10:2021/IS 17932: PART 6: 2023
160.		Test for Irritation	ISO 10993-23:2020/IS 17932: PART 7: 2023



Quality And Accreditation Institute

Centre for Laboratory Accreditation



Scope of Accreditation

Chemzin Biotox Research Institute Private Limited

1st Floor, Plot no-94, EPIP Ind. Area Phase-1, Jharmajri, Baddi

Solan-174103, Himachal Pradesh, India

QAI/CIA/TL/2026/0188

Valid from: 26 August 2026

Valid until: 25 August 2028

Accreditation Standard: ISO/IEC 17025:2017

Biological Testing			
Sl. No.	Product(s)/Material of Test	Specific Tests Performed	Test Method
	Medical Accessories & Surgical Products		
161.	Dental Products (Denture Teeth, Burs, Cements, Filling, Implants, Base Resins, Orthodontic Device, Tooth Brush, Permanent Crown, Braces)	Acute Systemic /Sub-Acute Systemic /Chronic/ Sub-Chronic Toxicity	ISO 10993-11:2017
162.		Cytotoxicity	ISO 10993-05:2009
163.		Hemocompatibility	ISO 10993-04:2017
164.		Genotoxicity	ISO 10993-03:2014
165.		Implantation Effects	ISO 10993-06:2026
166.		Material Mediated Pyrogenicity	ISO 10993-11:2017 (Annexure G)
167.		Skin Sensitization Test	ISO 10993-10:2021/IS 17932: PART 6: 2023
168.		Test for Irritation	ISO 10993-23:2020/IS 17932: PART 7: 2023
169.	Disposable & Surface Devices (Electrode Recording Probe, Hypodermic Needles, Infusion Set, Transfusion Set, Face Mask, Surgical Gown, PPE, Gloves, Urine Collection Bag, Hearing aid (Collar Ear Button, Paparella ear ventilation tubes), Hb Test Strips, Barrier Creams, ECG Gels,	Acute Systemic /Sub-Acute Systemic /Chronic/ Sub-Chronic Toxicity	ISO 10993-11:2017



Quality And Accreditation Institute

Centre for Laboratory Accreditation



Scope of Accreditation

Chemzin Biotox Research Institute Private Limited

1st Floor, Plot no-94, EPIP Ind. Area Phase-1, Jharmajri, Baddi

Solan-174103, Himachal Pradesh, India

QAI/CIA/TL/2026/0188

Valid from: 26 August 2026

Valid until: 25 August 2028

Accreditation Standard: ISO/IEC 17025:2017

Biological Testing			
Sl. No.	Product(s)/Material of Test	Specific Tests Performed	Test Method
	Medical Accessories & Surgical Products		
	EEG Gels, EP Paste, Sanitary Pads, Diapers, Blood Collection Bag)		
170.	Disposable & Surface Devices (Electrode Recording Probe, Hypodermic Needles, Infusion Set, Transfusion Set, Face Mask, Surgical Gown, PPE, Gloves, Urine Collection Bag, Hearing aid (Collar Ear Button, Paparella ear ventilation tubes), Hb Test Strips, Barrier Creams, ECG Gels, EEG Gels, EP Paste, Sanitary Pads, Diapers, Blood Collection Bag)	Cytotoxicity	ISO 10993-05:2009
171.		Hemocompatibility	ISO 10993-04:2017
172.		Genotoxicity	ISO 10993-03:2014
173.		Material Mediated Pyrogenicity	ISO 10993-11:2017 (Annexure G)
174.		Skin Sensitization Test	ISO 10993-10:2021/IS 17932: PART 6: 2023
175.		Test for Irritation	ISO 10993-23:2020/IS 17932: PART 7: 2023
176.	Dressing Material (Absorbent Cotton, Wound Surgical Cotton,	Cytotoxicity	ISO 10993-05:2009
177.	Bandages, Wound Surgical Bandages, Wound Protector,	Skin Sensitization Test	ISO 10993-10:2021/IS 17932: PART 6: 2023

This is annexure to 'Certificate of Accreditation' and does not require any signature.

www.qai.org.in



18 of 76

Quality And Accreditation Institute

Centre for Laboratory Accreditation



Scope of Accreditation

Chemzin Biotox Research Institute Private Limited

1st Floor, Plot no-94, EPIP Ind. Area Phase-1, Jharmajri, Baddi

Solan-174103, Himachal Pradesh, India

QAI/CIA/TL/2026/0188

Valid from: 26 August 2026

Valid until: 25 August 2028

Accreditation Standard: ISO/IEC 17025:2017

Biological Testing			
Sl. No.	Product(s)/Material of Test	Specific Tests Performed	Test Method
	Medical Accessories & Surgical Products		
178.	Wound Surgical Protector, Invo Vac Foam Dressing)	Test for Irritation	ISO 10993-23:2020/IS 17932: PART 7: 2023
179.	Endoscope (Ligation Device, Mucosal Resection, Bronchoscope, Laparoscope, Orthroscope, Laryngoscope, Stone Extraction Balloon)	Acute Systemic /Sub-Acute Systemic /Chronic/ Sub-Chronic Toxicity	ISO 10993-11:2017
180.	Endoscope (Ligation Device, Mucosal Resection, Bronchoscope, Laproscope, Orthroscope, Laryngoscope, Stone Extraction Balloon)	Cytotoxicity	ISO 10993-05:2009
181.	Endoscope (Ligation Device, Mucosal Resection, Bronchoscope, Laproscope, Orthroscope, Laryngoscope, Stone Extraction Balloon)	Hemocompatibility	ISO 10993-04:2017
182.	Endoscope (Ligation Device, Mucosal Resection, Bronchoscope, Laproscope, Orthroscope, Laryngoscope, Stone Extraction Balloon)	Genotoxicity	ISO 10993-03:2014



Quality And Accreditation Institute

Centre for Laboratory Accreditation



Scope of Accreditation

Chemzin Biotox Research Institute Private Limited

1st Floor, Plot no-94, EPIP Ind. Area Phase-1, Jharmajri, Baddi

Solan-174103, Himachal Pradesh, India

QAI/CIA/TL/2026/0188

Valid from: 26 August 2026

Valid until: 25 August 2028

Accreditation Standard: ISO/IEC 17025:2017

Biological Testing			
Sl. No.	Product(s)/Material of Test	Specific Tests Performed	Test Method
	Medical Accessories & Surgical Products		
183.	Bronchoscope, Laproscope, Orthroscope, Laryngoscope, Stone Extraction Balloon)	Material Mediated Pyrogenicity	ISO 10993-11:2017 (Annexure G)
184.	Endoscope (Ligation Device, Mucosal Resection, Bronchoscope, Laproscope, Orthroscope, Laryngoscope, Stone Extraction Balloon)	Skin Sensitization Test	ISO 10993-10:2021/IS 17932: PART 6: 2023
185.	Endoscope (Ligation Device, Mucosal Resection, Bronchoscope, Laproscope, Orthroscope, Laryngoscope, Stone Extraction Balloon)	Test for Irritation	ISO 10993-23:2020/IS 17932: PART 7: 2023
186.	Natural Orifice Devices (Natural Rubber Latex Condom, Latex Oral Dam, Intravaginal Devices, Intra uterine devices, Ligation Clips, Digital Thermometer)	Cytotoxicity	ISO 10993-05:2009
187.	Natural Orifice Devices (Natural Rubber Latex Condom, Latex Oral Dam, Intravaginal Devices, Intra uterine devices, Ligation Clips, Digital Thermometer)	Skin Sensitization Test	ISO 10993-10:2021/IS 17932: PART 6: 2023



Quality And Accreditation Institute

Centre for Laboratory Accreditation



Scope of Accreditation

Chemzin Biotox Research Institute Private Limited

1st Floor, Plot no-94, EPIP Ind. Area Phase-1, Jharmajri, Baddi

Solan-174103, Himachal Pradesh, India

QAI/CIA/TL/2026/0188

Valid from: 26 August 2026

Valid until: 25 August 2028

Accreditation Standard: ISO/IEC 17025:2017

Biological Testing			
Sl. No.	Product(s)/Material of Test	Specific Tests Performed	Test Method
	Medical Accessories & Surgical Products		
188.	Natural Orifice Devices (Natural Rubber Latex Condom, Latex Oral Dam, Intravaginal Devices, Intra uterine devices, Ligation Clips, Digital Thermometer)	Test for Irritation	ISO 10993-23:2020/IS 17932: PART 7: 2023
189.	Natural Orifice Devices (Natural Rubber Latex Condom, Latex Oral Dam, Intravaginal Devices, Intra uterine devices, Ligation Clips, Digital Thermometer)	Hemocompatibility	ISO 10993-04:2017
190.	Natural Orifice Devices (Natural Rubber Latex Condom, Latex Oral Dam, Intravaginal Devices, Intra uterine devices, Ligation Clips, Digital Thermometer)	Genotoxicity	ISO 10993-03:2014
191.	Natural Orifice Devices (Natural Rubber Latex Condom, Latex Oral Dam, Intravaginal Devices, Intra uterine devices, Ligation Clips, Digital Thermometer)	Material Mediated Pyrogenicity	ISO 10993-11:2017 (Annexure G)
192.	Natural Orifice Devices (Natural Rubber Latex Condom, Latex Oral Dam, Intravaginal Devices,	Acute Systemic /Sub-Acute Systemic /Chronic/ Sub-Chronic Toxicity	ISO 10993-11:2017



Quality And Accreditation Institute

Centre for Laboratory Accreditation



Scope of Accreditation

Chemzin Biotox Research Institute Private Limited

1st Floor, Plot no-94, EPIP Ind. Area Phase-1, Jharmajri, Baddi

Solan-174103, Himachal Pradesh, India

QAI/CIA/TL/2026/0188

Valid from: 26 August 2026

Valid until: 25 August 2028

Accreditation Standard: ISO/IEC 17025:2017

Biological Testing			
Sl. No.	Product(s)/Material of Test	Specific Tests Performed	Test Method
	Medical Accessories & Surgical Products		
	Intra uterine devices, Ligation Clips, Digital Thermometer)		
193.	Ophthalmic Products (Contact Lenses, Solutions, Inserts, Intraocular lenses, others)	Cytotoxicity	ISO 10993-05:2009
194.	Ophthalmic Products (Contact Lenses, Solutions, Inserts, Intraocular lenses, others)	Implantation Effects	ISO 10993-06:2026
195.	Ophthalmic Products (Contact Lenses, Solutions, Inserts, Intraocular lenses, others)	Skin Sensitization Test	ISO 10993-10:2021/IS 17932: PART 6: 2023
196.	Ophthalmic Products (Contact Lenses, Solutions, Inserts, Intraocular lenses, others)	Hemocompatibility	ISO 10993-04:2017
197.	Ophthalmic Products (Contact Lenses, Solutions, Inserts, Intraocular lenses, others)	Genotoxicity	ISO 10993-03:2014
198.	Ophthalmic Products (Contact Lenses, Solutions, Inserts, Intraocular lenses, others)	Material Mediated Pyrogenicity	ISO 10993-11:2017 (Annexure G)
199.	Ophthalmic Products (Contact Lenses, Solutions, Inserts, Intraocular lenses, others)	Acute Systemic /Sub-Acute Systemic /Chronic/ Sub-Chronic Toxicity	ISO 10993-11:2017



Quality And Accreditation Institute

Centre for Laboratory Accreditation



Scope of Accreditation

Chemzin Biotox Research Institute Private Limited

1st Floor, Plot no-94, EPIP Ind. Area Phase-1, Jharmajri, Baddi

Solan-174103, Himachal Pradesh, India

QAI/CIA/TL/2026/0188

Valid from: 26 August 2026

Valid until: 25 August 2028

Accreditation Standard: ISO/IEC 17025:2017

Biological Testing			
Sl. No.	Product(s)/Material of Test	Specific Tests Performed	Test Method
	Medical Accessories & Surgical Products		
200.	Ophthalmic Products (Contact Lenses, Solutions, Inserts, Intraocular lenses, others)	Hemocompatibility	ISO 10993-04:2017
201.	Ophthalmic Products (Contact Lenses, Solutions, Inserts, Intraocular lenses, others)	Genotoxicity	ISO 10993-03:2014
202.	Ophthalmic Products (Contact Lenses, Solutions, Inserts, Intraocular lenses, others)	Test for Irritation	ISO 10993-23:2020/IS 17932: PART 7: 2023
203.	Orthopedic (Moore's Pin, Pins, Plates, Screws, Small Joints, Wires, Interlocking Nails)	Acute Systemic /Sub-Acute Systemic /Chronic/ Sub-Chronic Toxicity	ISO 10993-11:2017
204.	Orthopedic (Moore's Pin, Pins, Plates, Screws, Small Joints, Wires, Interlocking Nails)	Cytotoxicity	ISO 10993-05:2009
205.	Orthopedic (Moore's Pin, Pins, Plates, Screws, Small Joints, Wires, Interlocking Nails)	Hemocompatibility	ISO 10993-04:2017
206.	Orthopedic (Moore's Pin, Pins, Plates, Screws, Small Joints, Wires, Interlocking Nails)	Genotoxicity	ISO 10993-03:2014
207.	Orthopedic (Moore's Pin, Pins, Plates, Screws, Small Joints, Wires, Interlocking Nails)	Implantation Effects	ISO 10993-06:2026



Quality And Accreditation Institute

Centre for Laboratory Accreditation



Scope of Accreditation

Chemzin Biotox Research Institute Private Limited

1st Floor, Plot no-94, EPIP Ind. Area Phase-1, Jharmajri, Baddi

Solan-174103, Himachal Pradesh, India

QAI/CIA/TL/2026/0188

Valid from: 26 August 2026

Valid until: 25 August 2028

Accreditation Standard: ISO/IEC 17025:2017

Biological Testing			
Sl. No.	Product(s)/Material of Test	Specific Tests Performed	Test Method
	Medical Accessories & Surgical Products		
208.	Orthopedic (Moore's Pin, Pins, Plates, Screws, Small Joints, Wires, Interlocking Nails)	Material Mediated Pyrogenicity	ISO 10993-11:2017 (Annexure G)
209.	Orthopedic (Moore's Pin, Pins, Plates, Screws, Small Joints, Wires, Interlocking Nails)	Skin Sensitization Test	ISO 10993-10:2021/IS 17932: PART 6: 2023
210.	Orthopedic (Moore's Pin, Pins, Plates, Screws, Small Joints, Wires, Interlocking Nails)	Test for Irritation	ISO 10993-23:2020/IS 17932: PART 7: 2023
211.	Polymers & Plastic Granules (Thermoplastic Rubber, Low Density Polyethylene, High Density Polyethylene, Rubber Products)	Acute Systemic /Sub-Acute Systemic /Chronic/ Sub-Chronic Toxicity	ISO 10993-11:2017
212.	Polymers & Plastic Granules (Thermoplastic Rubber, Low Density Polyethylene, High Density Polyethylene, Rubber Products)	Hemocompatibility	ISO 10993-04:2017
213.	Polymers & Plastic Granules (Thermoplastic Rubber, Low Density Polyethylene, High Density Polyethylene, Rubber Products)	Genotoxicity	ISO 10993-03:2014



Quality And Accreditation Institute

Centre for Laboratory Accreditation



Scope of Accreditation

Chemzin Biotox Research Institute Private Limited

1st Floor, Plot no-94, EPIP Ind. Area Phase-1, Jharmajri, Baddi

Solan-174103, Himachal Pradesh, India

QAI/CIA/TL/2026/0188

Valid from: 26 August 2026

Valid until: 25 August 2028

Accreditation Standard: ISO/IEC 17025:2017

Biological Testing			
Sl. No.	Product(s)/Material of Test	Specific Tests Performed	Test Method
	Medical Accessories & Surgical Products		
214.	Polymers & Plastic Granules (Thermoplastic Rubber, Low Density Polyethylene, High Density Polyethylene, Rubber Products)	Implantation Effects	ISO 10993-06:2026
215.	Polymers & Plastic Granules (Thermoplastic Rubber, Low Density Polyethylene, High Density Polyethylene, Rubber Products)	Test for Irritation	ISO 10993-23:2020/IS 17932: PART 7: 2023
216.	Polymers & Plastic Granules (Thermoplastic Rubber, Low Density Polyethylene, High Density Polyethylene, Rubber Products)	Material Mediated Pyrogenicity	ISO 10993-11:2017 (Annexure G)
217.	Polymers & Plastic Granules (Thermoplastic Rubber, Low Density Polyethylene, High Density Polyethylene, Rubber Products)	Cytotoxicity	ISO 10993-05:2009
218.		Skin Sensitization Test	ISO 10993-10:2021/IS 17932: PART 6: 2023
219.		Acute Systemic /Sub-Acute Systemic /Chronic/ Sub-Chronic Toxicity	ISO 10993-11:2017
220.		Cytotoxicity	ISO 10993-05:2009



Quality And Accreditation Institute

Centre for Laboratory Accreditation



Scope of Accreditation

Chemzin Biotox Research Institute Private Limited

1st Floor, Plot no-94, EPIP Ind. Area Phase-1, Jharmajri, Baddi

Solan-174103, Himachal Pradesh, India

QAI/CIA/TL/2026/0188

Valid from: 26 August 2026

Valid until: 25 August 2028

Accreditation Standard: ISO/IEC 17025:2017

Biological Testing			
Sl. No.	Product(s)/Material of Test	Specific Tests Performed	Test Method
	Medical Accessories & Surgical Products		
221.	Polymers & Plastic Granules (Thermoplastic Rubber, Low Density Polyethylene, High Density Polyethylene, Rubber Products)	Implantation Effects	ISO 10993-06:2026
222.	Polymers & Plastic Granules (Thermoplastic Rubber, Low Density Polyethylene, High Density Polyethylene, Rubber Products)	Material Mediated Pyrogenicity	ISO 10993-11:2017 (Annexure G)
223.	Polymers & Plastic Granules (Thermoplastic Rubber, Low Density Polyethylene, High Density Polyethylene, Rubber Products)	Hemocompatibility	ISO 10993-04:2017
224.	Polymers & Plastic Granules (Thermoplastic Rubber, Low Density Polyethylene, High Density Polyethylene, Rubber Products)	Genotoxicity	ISO 10993-03:2014
225.		Skin Sensitization Test	ISO 10993-10:2021/IS 17932: PART 6: 2023
226.		Test for Irritation	ISO 10993-23:2020/IS 17932: PART 7: 2023



Quality And Accreditation Institute

Centre for Laboratory Accreditation



Scope of Accreditation

Chemzin Biotox Research Institute Private Limited

1st Floor, Plot no-94, EPIP Ind. Area Phase-1, Jharmajri, Baddi

Solan-174103, Himachal Pradesh, India

QAI/CIA/TL/2026/0188

Valid from: 26 August 2026

Valid until: 25 August 2028

Accreditation Standard: ISO/IEC 17025:2017

Biological Testing			
Sl. No.	Product(s)/Material of Test	Specific Tests Performed	Test Method
	Medical Accessories & Surgical Products		
227.	Respiratory devices (Oxygenator, Tubing & Accessories, Nebulizer Bottles, Nebulizer Mask, Other Nebulizers, Extra Corporal)	Acute Systemic /Sub-Acute Systemic /Chronic/ Sub-Chronic Toxicity	ISO 10993-11:2017
228.	Respiratory devices (Oxygenator, Tubing & Accessories, Nebulizer Bottles, Nebulizer Mask, Other Nebulizers, Extra Corporal)	Cytotoxicity	ISO 10993-05:2009
229.	Respiratory devices (Oxygenator, Tubing & Accessories, Nebulizer Bottles, Nebulizer Mask, Other Nebulizers, Extra Corporal)	Implantation Effects	ISO 10993-06:2026
230.	Respiratory devices (Oxygenator, Tubing & Accessories, Nebulizer Bottles, Nebulizer Mask, Other Nebulizers, Extra Corporal)	Material Mediated Pyrogenicity	ISO 10993-11:2017 (Annexure G)
231.		Skin Sensitization Test	ISO 10993-10:2021/IS 17932: PART 6: 2023
232.		Test for Irritation	ISO 10993-23:2020/IS 17932: PART 7: 2023



Quality And Accreditation Institute

Centre for Laboratory Accreditation



Scope of Accreditation

Chemzin Biotox Research Institute Private Limited

1st Floor, Plot no-94, EPIP Ind. Area Phase-1, Jharmajri, Baddi

Solan-174103, Himachal Pradesh, India

QAI/CIA/TL/2026/0188

Valid from: 26 August 2026

Valid until: 25 August 2028

Accreditation Standard: ISO/IEC 17025:2017

Biological Testing			
Sl. No.	Product(s)/Material of Test	Specific Tests Performed	Test Method
	Medical Accessories & Surgical Products		
233.	Respiratory devices (Oxygenator, Tubing & Accessories, Nebulizer Bottles, Nebulizer Mask, Other Nebulizers, Extra Corporal)	Hemocompatibility	ISO 10993-04:2017
234.	Respiratory devices (Oxygenator, Tubing & Accessories, Nebulizer Bottles, Nebulizer Mask, Other Nebulizers, Extra Corporal)	Genotoxicity	ISO 10993-03:2014
235.	Syringes & Needles (Syringes with Needles, Flush Syringe, Prefilled Syringe, Insulin Syringe, Hypodermic Syringes, Aspiration Needle, Hypodermic Needles, Injection Needles, IP Needle with Diamond Tip)	Acute Systemic /Sub-Acute Systemic /Chronic/ Sub-Chronic Toxicity	ISO 10993-11:2017
236.	Syringes & Needles (Syringes with Needles, Flush Syringe, Prefilled Syringe, Insulin Syringe, Hypodermic Syringes, Aspiration Needle, Hypodermic Needles, Injection Needles, IP Needle with Diamond Tip)	Cytotoxicity	ISO 10993-05:2009



Quality And Accreditation Institute

Centre for Laboratory Accreditation



Scope of Accreditation

Chemzin Biotox Research Institute Private Limited

1st Floor, Plot no-94, EPIP Ind. Area Phase-1, Jharmajri, Baddi

Solan-174103, Himachal Pradesh, India

QAI/CIA/TL/2026/0188

Valid from: 26 August 2026

Valid until: 25 August 2028

Accreditation Standard: ISO/IEC 17025:2017

Biological Testing			
Sl. No.	Product(s)/Material of Test	Specific Tests Performed	Test Method
	Medical Accessories & Surgical Products		
237.	Syringes & Needles (Syringes with Needles, Flush Syringe, Prefilled Syringe, Insulin Syringe, Hypodermic Syringes, Aspiration Needle, Hypodermic Needles, Injection Needles, IP Needle with Diamond Tip)	Hemocompatibility	ISO 10993-04:2017
238.	Syringes & Needles (Syringes with Needles, Flush Syringe, Prefilled Syringe, Insulin Syringe, Hypodermic Syringes, Aspiration Needle, Hypodermic Needles, Injection Needles, IP Needle with Diamond Tip)	Genotoxicity	ISO 10993-03:2014
239.	Syringes & Needles (Syringes with Needles, Flush Syringe, Prefilled Syringe, Insulin Syringe, Hypodermic Syringes, Aspiration Needle, Hypodermic Needles, Injection Needles, IP Needle with Diamond Tip)	Material Mediated Pyrogenicity	ISO 10993-11:2017 (Annexure G)
240.		Skin Sensitization Test	ISO 10993-10:2021/IS 17932: PART 6: 2023
241.		Test for Irritation	ISO 10993-23:2020/IS 17932: PART 7: 2023



Quality And Accreditation Institute

Centre for Laboratory Accreditation



Scope of Accreditation

Chemzin Biotox Research Institute Private Limited

1st Floor, Plot no-94, EPIP Ind. Area Phase-1, Jharmajri, Baddi

Solan-174103, Himachal Pradesh, India

QAI/CIA/TL/2026/0188

Valid from: 26 August 2026

Valid until: 25 August 2028

Accreditation Standard: ISO/IEC 17025:2017

Biological Testing			
Sl. No.	Product(s)/Material of Test	Specific Tests Performed	Test Method
	Medical Accessories & Surgical Products		
242.	Syringes & Needles (Syringes with Needles, Flush Syringe, Prefilled Syringe, Insulin Syringe, Hypodermic Syringes, Aspiration Needle, Hypodermic Needles, Injection Needles, IP Needle with Diamond Tip)	Hemocompatibility	ISO 10993-04:2017
243.	Syringes & Needles (Syringes with Needles, Flush Syringe, Prefilled Syringe, Insulin Syringe, Hypodermic Syringes, Aspiration Needle, Hypodermic Needles, Injection Needles, IP Needle with Diamond Tip)	Genotoxicity	ISO 10993-03:2014
244.	Test for Injection- Antibiotics, Anticancer Drug, Haematinics, Heparin Antidote, Fibrinolytic enzymes, Thrombolytic agents, Purified protein derivatives, Vaccines, Antisera & immunoglobulins.	Abnormal Toxicity	IP (2022) Chapter 2.2.1
245.	Tubes (Infant Feeding, Ryles, Endotracheal, Drainage Set, Closed Wound Drainage Tube, Dialysis Tubes & Accessories,	Acute Systemic /Sub-Acute Systemic /Chronic/ Sub-Chronic Toxicity	ISO 10993-11:2017

This is annexure to 'Certificate of Accreditation' and does not require any signature.

www.qai.org.in



30 of 76

Quality And Accreditation Institute

Centre for Laboratory Accreditation



Scope of Accreditation

Chemzin Biotox Research Institute Private Limited

1st Floor, Plot no-94, EPIP Ind. Area Phase-1, Jharmajri, Baddi

Solan-174103, Himachal Pradesh, India

QAI/CIA/TL/2026/0188

Valid from: 26 August 2026

Valid until: 25 August 2028

Accreditation Standard: ISO/IEC 17025:2017

Biological Testing			
Sl. No.	Product(s)/Material of Test	Specific Tests Performed	Test Method
	Medical Accessories & Surgical Products		
	Transfusion Sets, Solution & Blood Administration Set, Manifolds, 3 Way Stop Cock & Extension Line)		
246.	Tubes (Infant Feeding, Ryles, Endotracheal, Drainage Set, Closed Wound Drainage Tube, Dialysis Tubes & Accessories, Transfusion Sets, Solution & Blood Administration Set, Manifolds, 3 Way Stop Cock & Extension Line)	Cytotoxicity	ISO 10993-05:2009
247.	Tubes (Infant Feeding, Ryles, Endotracheal, Drainage Set, Closed Wound Drainage Tube, Dialysis Tubes & Accessories, Transfusion Sets, Solution & Blood Administration Set, Manifolds, 3 Way Stop Cock & Extension Line)	Hemocompatibility	ISO 10993-04:2017
248.	Tubes (Infant Feeding, Ryles, Endotracheal, Drainage Set, Closed Wound Drainage Tube, Dialysis Tubes & Accessories, Transfusion Sets, Solution &	Genotoxicity	ISO 10993-03:2014

This is annexure to 'Certificate of Accreditation' and does not require any signature.

www.qai.org.in



31 of 76

Quality And Accreditation Institute

Centre for Laboratory Accreditation



Scope of Accreditation

Chemzin Biotox Research Institute Private Limited

1st Floor, Plot no-94, EPIP Ind. Area Phase-1, Jharmajri, Baddi

Solan-174103, Himachal Pradesh, India

QAI/CIA/TL/2026/0188

Valid from: 26 August 2026

Valid until: 25 August 2028

Accreditation Standard: ISO/IEC 17025:2017

Biological Testing			
Sl. No.	Product(s)/Material of Test	Specific Tests Performed	Test Method
	Medical Accessories & Surgical Products		
	Blood Administration Set, Manifolds, 3 Way Stop Cock & Extension Line)		
249.	Tubes (Infant Feeding, Ryles, Endotracheal, Drainage Set, Closed Wound Drainage Tube, Dialysis Tubes & Accessories, Transfusion Sets, Solution & Blood Administration Set, Manifolds, 3 Way Stop Cock & Extension Line)	Material Mediated Pyrogenicity	ISO 10993-11:2017 (Annexure G)
250.	Tubes (Infant Feeding, Ryles, Endotracheal, Drainage Set, Closed Wound Drainage Tube, Dialysis Tubes & Accessories, Transfusion Sets, Solution & Blood Administration Set, Manifolds, 3 Way Stop Cock & Extension Line)	Skin Sensitization Test	ISO 10993-10:2021/IS 17932: PART 6: 2023
251.	Tubes (Infant Feeding, Ryles, Endotracheal, Drainage Set, Closed Wound Drainage Tube, Dialysis Tubes & Accessories, Transfusion Sets, Solution & Blood Administration Set,	Test for Irritation	ISO 10993-23:2020/IS 17932: PART 7: 2023

This is annexure to 'Certificate of Accreditation' and does not require any signature.

www.qai.org.in



32 of 76

Quality And Accreditation Institute

Centre for Laboratory Accreditation



Scope of Accreditation

Chemzin Biotox Research Institute Private Limited

1st Floor, Plot no-94, EPIP Ind. Area Phase-1, Jharmajri, Baddi

Solan-174103, Himachal Pradesh, India

QAI/CIA/TL/2026/0188

Valid from: 26 August 2026

Valid until: 25 August 2028

Accreditation Standard: ISO/IEC 17025:2017

Biological Testing			
Sl. No.	Product(s)/Material of Test	Specific Tests Performed	Test Method
	Medical Accessories & Surgical Products		
	Manifolds, 3 Way Stop Cock & Extension Line)		
252.	Guiding catheters for cardiac catheterization procedures	Acute Systemic /Sub-Acute Systemic /Chronic/ Sub-Chronic Toxicity	ISO 10993-11:2017
253.	Guiding catheters for cardiac catheterization procedures	Cytotoxicity	ISO 10993-05:2009
254.	Guiding catheters for cardiac catheterization procedures	Implantation Effects	ISO 10993-06:2026
255.	Guiding catheters for cardiac catheterization procedures	Hemocompatibility	ISO 10993-04:2017
256.	Guiding catheters for cardiac catheterization procedures	Genotoxicity	ISO 10993-03:2014
257.	Guiding catheters for cardiac catheterization procedures	Material Mediated Pyrogenicity	ISO 10993-11:2017 (Annexure G)
258.	Guiding catheters for cardiac catheterization procedures	Skin Sensitization Test	ISO 10993-10:2021/IS 17932: PART 6 : 2023
259.	Guiding catheters for cardiac catheterization procedures	Test for Irritation	ISO 10993-23:2020/IS 17932: PART 7: 2023
260.	Dilatation catheters (balloon dilatation catheters) for widen narrowed or blocked passages in the body	Acute Systemic /Sub-Acute Systemic /Chronic/ Sub-Chronic Toxicity	ISO 10993-11:2017



Quality And Accreditation Institute

Centre for Laboratory Accreditation



Scope of Accreditation

Chemzin Biotox Research Institute Private Limited

1st Floor, Plot no-94, EPIP Ind. Area Phase-1, Jharmajri, Baddi

Solan-174103, Himachal Pradesh, India

QAI/CIA/TL/2026/0188

Valid from: 26 August 2026

Valid until: 25 August 2028

Accreditation Standard: ISO/IEC 17025:2017

Biological Testing			
Sl. No.	Product(s)/Material of Test	Specific Tests Performed	Test Method
	Medical Accessories & Surgical Products		
261.	Dilatation catheters (balloon dilatation catheters) for widen narrowed or blocked passages in the body	Cytotoxicity	ISO 10993-05:2009
262.	Dilatation catheters (balloon dilatation catheters) for widen narrowed or blocked passages in the body	Implantation Effects	ISO 10993-06:2026
263.	Dilatation catheters (balloon dilatation catheters) for widen narrowed or blocked passages in the body	Hemocompatibility	ISO 10993-04:2017
264.	Dilatation catheters (balloon dilatation catheters) for widen narrowed or blocked passages in the body	Genotoxicity	ISO 10993-03:2014
265.	Dilatation catheters (balloon dilatation catheters) for widen narrowed or blocked passages in the body	Material Mediated Pyrogenicity	ISO 10993-11:2017 (Annexure G)
266.	Dilatation catheters (balloon dilatation catheters) for widen narrowed or blocked passages in the body	Skin Sensitization Test	ISO 10993-10:2021/IS 17932: PART 6: 2023



Quality And Accreditation Institute

Centre for Laboratory Accreditation



Scope of Accreditation

Chemzin Biotox Research Institute Private Limited

1st Floor, Plot no-94, EPIP Ind. Area Phase-1, Jharmajri, Baddi

Solan-174103, Himachal Pradesh, India

QAI/CIA/TL/2026/0188

Valid from: 26 August 2026

Valid until: 25 August 2028

Accreditation Standard: ISO/IEC 17025:2017

Biological Testing			
Sl. No.	Product(s)/Material of Test	Specific Tests Performed	Test Method
	Medical Accessories & Surgical Products		
267.	Dilatation catheters (balloon dilatation catheters) for widen narrowed or blocked passages in the body	Test for Irritation	ISO 10993-23:2020/IS 17932: PART 7: 2023
268.	Hemodialysis catheters for provide temporary or long-term access to bloodstream (Dual lumen catheter, Vessel Dilator, Injection caps, Normal syringe 10ml, Medifix, Tunneler, Cotton Gauze Sponge, Scalpel, Introducer Needle, Material Sheet, Surgical Needled Suture)	Acute Systemic /Sub-Acute Systemic /Chronic/ Sub-Chronic Toxicity	ISO 10993-11:2017
269.	Hemodialysis catheters for provide temporary or long-term access to bloodstream (Dual lumen catheter, Vessel Dilator, Injection caps, Normal syringe 10ml, Medifix, Tunneler, Cotton Gauze Sponge, Scalpel, Introducer Needle, Material Sheet, Surgical Needled Suture)	Cytotoxicity	ISO 10993-05:2009
270.	Hemodialysis catheters for provide temporary or long-term access to bloodstream (Dual	Implantation Effects	ISO 10993-06:2026

This is annexure to 'Certificate of Accreditation' and does not require any signature.

www.qai.org.in



35 of 76

Quality And Accreditation Institute

Centre for Laboratory Accreditation



Scope of Accreditation

Chemzin Biotox Research Institute Private Limited

1st Floor, Plot no-94, EPIP Ind. Area Phase-1, Jharmajri, Baddi

Solan-174103, Himachal Pradesh, India

QAI/CIA/TL/2026/0188

Valid from: 26 August 2026

Valid until: 25 August 2028

Accreditation Standard: ISO/IEC 17025:2017

Biological Testing			
Sl. No.	Product(s)/Material of Test	Specific Tests Performed	Test Method
	Medical Accessories & Surgical Products		
	lumen catheter, Vessel Dilator, Injection caps, Normal syringe 10ml, Medifix, Tunneler, Cotton Gauze Sponge, Scalpel, Introducer Needle, Material Sheet, Surgical Needled Suture)		
271.	Hemodialysis catheters for provide temporary or long-term access to bloodstream (Dual lumen catheter, Vessel Dilator, Injection caps, Normal syringe 10ml, Medifix, Tunneler, Cotton Gauze Sponge, Scalpel, Introducer Needle, Material Sheet, Surgical Needled Suture)	Hemocompatibility	ISO 10993-04:2017
272.	Hemodialysis catheters for provide temporary or long-term access to bloodstream (Dual lumen catheter, Vessel Dilator, Injection caps, Normal syringe 10ml, Medifix, Tunneler, Cotton Gauze Sponge, Scalpel, Introducer Needle, Material Sheet, Surgical Needled Suture)	Genotoxicity	ISO 10993-03:2014



Quality And Accreditation Institute

Centre for Laboratory Accreditation



Scope of Accreditation

Chemzin Biotox Research Institute Private Limited

1st Floor, Plot no-94, EPIP Ind. Area Phase-1, Jharmajri, Baddi

Solan-174103, Himachal Pradesh, India

QAI/CIA/TL/2026/0188

Valid from: 26 August 2026

Valid until: 25 August 2028

Accreditation Standard: ISO/IEC 17025:2017

Biological Testing			
Sl. No.	Product(s)/Material of Test	Specific Tests Performed	Test Method
	Medical Accessories & Surgical Products		
273.	Hemodialysis catheters for provide temporary or long-term access to bloodstream (Dual lumen catheter, Vessel Dilator, Injection caps, Normal syringe 10ml, Medifix, Tunneler, Cotton Gauze Sponge, Scalpel, Introducer Needle, Material Sheet, Surgical Needled Suture)	Material Mediated Pyrogenicity	ISO 10993-11:2017 (Annexure G)
274.	Hemodialysis catheters for provide temporary or long-term access to bloodstream (Dual lumen catheter, Vessel Dilator, Injection caps, Normal syringe 10ml, Medifix, Tunneler, Cotton Gauze Sponge, Scalpel, Introducer Needle, Material Sheet, Surgical Needled Suture)	Skin Sensitization Test	ISO 10993-10:2021/IS 17932: PART 6: 2023
275.	Hemodialysis catheters for provide temporary or long-term access to bloodstream (Dual lumen catheter, Vessel Dilator, Injection caps, Normal syringe 10ml, Medifix, Tunneler, Cotton Gauze Sponge, Scalpel,	Test for Irritation	ISO 10993-23:2020/IS 17932: PART 7: 2023

This is annexure to 'Certificate of Accreditation' and does not require any signature.

www.qai.org.in



37 of 76

Quality And Accreditation Institute

Centre for Laboratory Accreditation



Scope of Accreditation

Chemzin Biotox Research Institute Private Limited

1st Floor, Plot no-94, EPIP Ind. Area Phase-1, Jharmajri, Baddi

Solan-174103, Himachal Pradesh, India

QAI/CIA/TL/2026/0188

Valid from: 26 August 2026

Valid until: 25 August 2028

Accreditation Standard: ISO/IEC 17025:2017

Biological Testing			
Sl. No.	Product(s)/Material of Test	Specific Tests Performed	Test Method
	Medical Accessories & Surgical Products		
	Introducer Needle, Material Sheet, Surgical Needled Suture)		
276.	Dilatation catheters– SC (balloon dilatation catheters) for widen narrowed or blocked passages in the body	Acute Systemic /Sub-Acute Systemic /Chronic/ Sub-Chronic Toxicity	ISO 10993-11:2017
277.	Dilatation catheters– SC (balloon dilatation catheters) for widen narrowed or blocked passages in the body	Cytotoxicity	ISO 10993-05:2009
278.	Dilatation catheters– SC (balloon dilatation catheters) for widen narrowed or blocked passages in the body	Implantation Effects	ISO 10993-06:2026
279.	Dilatation catheters– SC (balloon dilatation catheters) for widen narrowed or blocked passages in the body	Hemocompatibility	ISO 10993-04:2017
280.	Dilatation catheters– SC (balloon dilatation catheters) for widen narrowed or blocked passages in the body	Genotoxicity	ISO 10993-03:2014



Quality And Accreditation Institute

Centre for Laboratory Accreditation



Scope of Accreditation

Chemzin Biotox Research Institute Private Limited

1st Floor, Plot no-94, EPIP Ind. Area Phase-1, Jharmajri, Baddi

Solan-174103, Himachal Pradesh, India

QAI/CIA/TL/2026/0188

Valid from: 26 August 2026

Valid until: 25 August 2028

Accreditation Standard: ISO/IEC 17025:2017

Biological Testing			
Sl. No.	Product(s)/Material of Test	Specific Tests Performed	Test Method
	Medical Accessories & Surgical Products		
281.	Dilatation catheters– SC (balloon dilatation catheters) for widen narrowed or blocked passages in the body	Material Mediated Pyrogenicity	ISO 10993-11:2017 (Annexure G)
282.	Dilatation catheters– SC (balloon dilatation catheters) for widen narrowed or blocked passages in the body	Skin Sensitization Test	ISO 10993-10:2021/IS 17932: PART 6: 2023
283.	Dilatation catheters– SC (balloon dilatation catheters) for widen narrowed or blocked passages in the body	Test for Irritation	ISO 10993-23:2020/IS 17932: PART 7: 2023
284.	Insulin Pen Needles	MTT (3-(4,5-dimethylthiazol-2-yl)-2,5-diphenyltetrazoliumbromid) Assay	ISO 10993-5:2009, OECD 129
285.	Insulin Pen Needles	NRU (Neutral Red Uptake)	ISO 10993-5:2009, OECD 129
286.	Insulin Pen Needles	XTT (2,3-bis-(2-methoxy-4-nitro-5-sulphophenyl)-2H-tetrazolium-5-carboxanilide)	ISO 10993-5:2009
287.	Insulin Pen Needles	Cytotoxicity (MEM)	ISO 10993-5:2009
288.	Positioner for CABG	MTT (3-(4,5-dimethylthiazol-2-yl)-2,5-diphenyltetrazoliumbromid) Assay	ISO 10993-5:2009, OECD 129



Quality And Accreditation Institute

Centre for Laboratory Accreditation



Scope of Accreditation

Chemzin Biotox Research Institute Private Limited

1st Floor, Plot no-94, EPIP Ind. Area Phase-1, Jharmajri, Baddi

Solan-174103, Himachal Pradesh, India

QAI/CIA/TL/2026/0188

Valid from: 26 August 2026

Valid until: 25 August 2028

Accreditation Standard: ISO/IEC 17025:2017

Biological Testing			
Sl. No.	Product(s)/Material of Test	Specific Tests Performed	Test Method
	Medical Accessories & Surgical Products		
289.	Positioner for CABG	NRU (Neutral Red Uptake)	ISO 10993-5:2009, OECD 129
290.	Positioner for CABG	XTT (2,3-bis-(2-methoxy-4-nitro-5-sulphophenyl)-2H-tetrazolium-5-carboxanilide)	ISO 10993-5:2009
291.	Positioner for CABG	Cytotoxicity (MEM)	ISO 10993-5:2009
292.	Blood Separating bottles	MTT (3-(4,5-dimethylthiazol-2-yl)-2,5-diphenyltetrazoliumbromid) Assay	ISO 10993-5:2009, OECD 129
293.	Blood Separating bottles	NRU (Neutral Red Uptake)	ISO 10993-5:2009, OECD 129
294.	Blood Separating bottles	XTT (2,3-bis-(2-methoxy-4-nitro-5-sulphophenyl)-2H-tetrazolium-5-carboxanilide)	ISO 10993-5:2009
295.	Blood Separating bottles	Cytotoxicity (MEM)	ISO 10993-5:2009
296.	Bone Implants	MTT (3-(4,5-dimethylthiazol-2-yl)-2,5-diphenyltetrazoliumbromid) Assay	ISO 10993-5:2009
297.	Bone Implants	NRU (Neutral Red Uptake)	ISO 10993-5:2009, OECD 129
298.	Bone Implants	XTT (2,3-bis-(2-methoxy-4-nitro-5-sulphophenyl)-2H-tetrazolium-5-carboxanilide)	ISO 10993-5:2009
299.	Bone Implants	Cytotoxicity (MEM)	ISO 10993-5:2009



Quality And Accreditation Institute

Centre for Laboratory Accreditation



Scope of Accreditation

Chemzin Biotox Research Institute Private Limited

1st Floor, Plot no-94, EPIP Ind. Area Phase-1, Jharmajri, Baddi

Solan-174103, Himachal Pradesh, India

QAI/CIA/TL/2026/0188

Valid from: 26 August 2026

Valid until: 25 August 2028

Accreditation Standard: ISO/IEC 17025:2017

Biological Testing			
Sl. No.	Product(s)/Material of Test	Specific Tests Performed	Test Method
	Medical Accessories & Surgical Products		
300.	Orthopaedic screws	MTT (3-(4,5-dimethylthiazol-2-yl)-2,5-diphenyltetrazoliumbromid) Assay	ISO 10993-5:2009
301.	Orthopaedic screws	NRU (Neutral Red Uptake)	ISO 10993-5:2009, OECD 129
302.	Orthopaedic screws	XTT (2,3-bis-(2-methoxy-4-nitro-5-sulfophenyl)-2H-tetrazolium-5-carboxanilide)	ISO 10993-5:2009
303.	Orthopaedic screws	Cytotoxicity (MEM)	ISO 10993-5:2009
304.	Orthopaedic prosthesis	MTT (3-(4,5-dimethylthiazol-2-yl)-2,5-diphenyltetrazoliumbromid) Assay	ISO 10993-5:2009
305.	Orthopaedic prosthesis	NRU (Neutral Red Uptake)	ISO 10993-5:2009, OECD 129
306.	Orthopaedic prosthesis	XTT (2,3-bis-(2-methoxy-4-nitro-5-sulfophenyl)-2H-tetrazolium-5-carboxanilide)	ISO 10993-5:2009, OECD 129
307.	Orthopaedic prosthesis	Cytotoxicity (MEM)	ISO 10993-5:2009
308.	Orthopaedic pins	MTT (3-(4,5-dimethylthiazol-2-yl)-2,5-diphenyltetrazoliumbromid) Assay	ISO 10993-5:2009
309.	Orthopaedic pins	NRU (Neutral Red Uptake)	ISO 10993-5:2009,



Quality And Accreditation Institute

Centre for Laboratory Accreditation



Scope of Accreditation

Chemzin Biotox Research Institute Private Limited

1st Floor, Plot no-94, EPIP Ind. Area Phase-1, Jharmajri, Baddi

Solan-174103, Himachal Pradesh, India

QAI/CIA/TL/2026/0188

Valid from: 26 August 2026

Valid until: 25 August 2028

Accreditation Standard: ISO/IEC 17025:2017

Biological Testing			
Sl. No.	Product(s)/Material of Test	Specific Tests Performed	Test Method
	Medical Accessories & Surgical Products		
310.	Orthopaedic pins	XTT (2,3-bis-(2-methoxy-4-nitro-5-sulfophenyl)-2H-tetrazolium-5-carboxanilide)	ISO 10993-5:2009, OECD 129
311.	Orthopaedic pins	Cytotoxicity (MEM)	ISO 10993-5:2009
312.	Orthopaedic Plates	MTT (3-(4,5-dimethylthiazol-2-yl)-2,5-diphenyltetrazoliumbromid) Assay	ISO 10993-5:2009
313.	Orthopaedic Plates	NRU (Neutral Red Uptake)	ISO 10993-5:2009,
314.	Orthopaedic Plates	XTT (2,3-bis-(2-methoxy-4-nitro-5-sulfophenyl)-2H-tetrazolium-5-carboxanilide)	ISO 10993-5:2009, OECD 129
315.	Orthopaedic Plates	Cytotoxicity (MEM)	ISO 10993-5:2009
316.	Orthopaedic wires	MTT (3-(4,5-dimethylthiazol-2-yl)-2,5-diphenyltetrazoliumbromid) Assay	ISO 10993-5:2009
317.	Orthopaedic wires	NRU (Neutral Red Uptake)	ISO 10993-5:2009,
318.	Orthopaedic wires	XTT (2,3-bis-(2-methoxy-4-nitro-5-sulfophenyl)-2H-tetrazolium-5-carboxanilide)	ISO 10993-5:2009, OECD 129
319.	Orthopaedic wires	Cytotoxicity (MEM)	ISO 10993-5:2009



Quality And Accreditation Institute

Centre for Laboratory Accreditation



Scope of Accreditation

Chemzin Biotox Research Institute Private Limited

1st Floor, Plot no-94, EPIP Ind. Area Phase-1, Jharmajri, Baddi

Solan-174103, Himachal Pradesh, India

QAI/CIA/TL/2026/0188

Valid from: 26 August 2026

Valid until: 25 August 2028

Accreditation Standard: ISO/IEC 17025:2017

Biological Testing			
Sl. No.	Product(s)/Material of Test	Specific Tests Performed	Test Method
	Medical Accessories & Surgical Products		
320.	Rubber Stoppers	MTT (3-(4,5-dimethylthiazol-2-yl)-2,5-diphenyltetrazoliumbromid) Assay	ISO 10993-5:2009
321.	Rubber Stoppers	NRU (Neutral Red Uptake)	ISO 10993-5:2009,
322.	Rubber Stoppers	XTT (2,3-bis-(2-methoxy-4-nitro-5-sulfophenyl)-2H-tetrazolium-5-carboxanilide)	ISO 10993-5:2009, OECD 129
323.	Rubber Stoppers	Cytotoxicity (MEM)	ISO 10993-5:2009
324.	Ryles Tube	MTT (3-(4,5-dimethylthiazol-2-yl)-2,5-diphenyltetrazoliumbromid) Assay	ISO 10993-5:2009
325.	Ryles Tube	NRU (Neutral Red Uptake)	ISO 10993-5:2009,
326.	Ryles Tube	XTT (2,3-bis-(2-methoxy-4-nitro-5-sulfophenyl)-2H-tetrazolium-5-carboxanilide)	ISO 10993-5:2009, OECD 129
327.	Ryles Tube	Cytotoxicity (MEM)	ISO 10993-5:2009
328.	Mesh for Muscles	MTT (3-(4,5-dimethylthiazol-2-yl)-2,5-diphenyltetrazoliumbromid) Assay	ISO 10993-5:2009
329.	Mesh for Muscles	NRU (Neutral Red Uptake)	ISO 10993-5:2009,



Quality And Accreditation Institute

Centre for Laboratory Accreditation



Scope of Accreditation

Chemzin Biotox Research Institute Private Limited

1st Floor, Plot no-94, EPIP Ind. Area Phase-1, Jharmajri, Baddi

Solan-174103, Himachal Pradesh, India

QAI/CIA/TL/2026/0188

Valid from: 26 August 2026

Valid until: 25 August 2028

Accreditation Standard: ISO/IEC 17025:2017

Biological Testing			
Sl. No.	Product(s)/Material of Test	Specific Tests Performed	Test Method
	Medical Accessories & Surgical Products		
330.	Mesh for Muscles	XTT (2,3-bis-(2-methoxy-4-nitro-5-sulfophenyl)-2H-tetrazolium-5-carboxanilide)	ISO 10993-5:2009, OECD 129
331.	Mesh for Muscles	Cytotoxicity (MEM)	ISO 10993-5:2009
332.	Cannula	MTT (3-(4,5-dimethylthiazol-2-yl)-2,5-diphenyltetrazoliumbromid) Assay	ISO 10993-5:2009
333.	Cannula	NRU (Neutral Red Uptake)	ISO 10993-5:2009,
334.	Cannula	XTT (2,3-bis-(2-methoxy-4-nitro-5-sulfophenyl)-2H-tetrazolium-5-carboxanilide)	ISO 10993-5:2009, OECD 129
335.	Cannula	Cytotoxicity (MEM)	ISO 10993-5:2009
336.	Sutures	MTT (3-(4,5-dimethylthiazol-2-yl)-2,5-diphenyltetrazoliumbromid) Assay	ISO 10993-5:2009,
337.	Sutures	NRU (Neutral Red Uptake)	ISO 10993-5:2009, OECD 129
338.	Sutures	XTT (2,3-bis-(2-methoxy-4-nitro-5-sulfophenyl)-2H-tetrazolium-5-carboxanilide)	ISO 10993-5:2009, OECD 129
339.	Sutures	Cytotoxicity (MEM)	ISO 10993-5:2009



Quality And Accreditation Institute

Centre for Laboratory Accreditation



Scope of Accreditation

Chemzin Biotox Research Institute Private Limited

1st Floor, Plot no-94, EPIP Ind. Area Phase-1, Jharmajri, Baddi

Solan-174103, Himachal Pradesh, India

QAI/CIA/TL/2026/0188

Valid from: 26 August 2026

Valid until: 25 August 2028

Accreditation Standard: ISO/IEC 17025:2017

Biological Testing			
Sl. No.	Product(s)/Material of Test	Specific Tests Performed	Test Method
	Medical Accessories & Surgical Products		
340.	Catheter	MTT (3-(4,5-dimethylthiazol-2-yl)-2,5-diphenyltetrazoliumbromid) Assay	ISO 10993-5:2009,
341.	Catheter	NRU (Neutral Red Uptake)	ISO 10993-5:2009, OECD 129
342.	Catheter	XTT (2,3-bis-(2-methoxy-4-nitro-5-sulfophenyl)-2H-tetrazolium-5-carboxanilide)	ISO 10993-5:2009, OECD 129
343.	Catheter	Cytotoxicity (MEM)	ISO 10993-5:2009
344.	Fat Binder tablets	MTT (3-(4,5-dimethylthiazol-2-yl)-2,5-diphenyltetrazoliumbromid) Assay	ISO 10993-5:2009,
345.	Fat Binder tablets	NRU (Neutral Red Uptake)	ISO 10993-5:2009, OECD 129
346.	Fat Binder tablets	XTT (2,3-bis-(2-methoxy-4-nitro-5-sulfophenyl)-2H-tetrazolium-5-carboxanilide)	ISO 10993-5:2009, OECD 129
347.	Fat Binder tablets	Cytotoxicity (MEM)	ISO 10993-5:2009
348.	Throat lozenges	MTT (3-(4,5-dimethylthiazol-2-yl)-2,5-diphenyltetrazoliumbromid) Assay	ISO 10993-5:2009,
349.	Throat lozenges	NRU (Neutral Red Uptake)	ISO 10993-5:2009, OECD 129



Quality And Accreditation Institute

Centre for Laboratory Accreditation



Scope of Accreditation

Chemzin Biotox Research Institute Private Limited

1st Floor, Plot no-94, EPIP Ind. Area Phase-1, Jharmajri, Baddi

Solan-174103, Himachal Pradesh, India

QAI/CIA/TL/2026/0188

Valid from: 26 August 2026

Valid until: 25 August 2028

Accreditation Standard: ISO/IEC 17025:2017

Biological Testing			
Sl. No.	Product(s)/Material of Test	Specific Tests Performed	Test Method
	Medical Accessories & Surgical Products		
350.	Throat lozenges	XTT (2,3-bis-(2-methoxy-4-nitro-5-sulfophenyl)-2H-tetrazolium-5-carboxanilide)	ISO 10993-5:2009, OECD 129
351.	Throat lozenges	Cytotoxicity (MEM)	ISO 10993-5:2009
352.	Nasal Gel for prevention of Epistaxis	MTT (3-(4,5-dimethylthiazol-2-yl)-2,5-diphenyltetrazoliumbromid) Assay	ISO 10993-5:2009,
353.	Nasal Gel for prevention of Epistaxis	NRU (Neutral Red Uptake)	ISO 10993-5:2009, OECD 129
354.	Nasal Gel for prevention of Epistaxis	XTT (2,3-bis-(2-methoxy-4-nitro-5-sulfophenyl)-2H-tetrazolium-5-carboxanilide)	ISO 10993-5:2009, OECD 129
355.	Nasal Gel for prevention of Epistaxis	Cytotoxicity (MEM)	ISO 10993-5:2009
356.	Nasal tube for sinus drainage	MTT (3-(4,5-dimethylthiazol-2-yl)-2,5-diphenyltetrazoliumbromid) Assay	ISO 10993-5:2009,
357.	Nasal tube for sinus drainage	NRU (Neutral Red Uptake)	ISO 10993-5:2009, OECD 129
358.	Nasal tube for sinus drainage	XTT (2,3-bis-(2-methoxy-4-nitro-5-sulfophenyl)-2H-tetrazolium-5-carboxanilide)	ISO 10993-5:2009, OECD 129
359.	Nasal tube for sinus drainage	Cytotoxicity (MEM)	ISO 10993-5:2009



Quality And Accreditation Institute

Centre for Laboratory Accreditation



Scope of Accreditation

Chemzin Biotox Research Institute Private Limited

1st Floor, Plot no-94, EPIP Ind. Area Phase-1, Jharmajri, Baddi

Solan-174103, Himachal Pradesh, India

QAI/CIA/TL/2026/0188

Valid from: 26 August 2026

Valid until: 25 August 2028

Accreditation Standard: ISO/IEC 17025:2017

Biological Testing			
Sl. No.	Product(s)/Material of Test	Specific Tests Performed	Test Method
	Medical Accessories & Surgical Products		
360.	Biopsy & Surgical Devices (Scalpels, Hemostat, Forcep, Needle Kit, Surgical Blades, Scissors, Suture)	MTT (3-(4,5-dimethylthiazol-2-yl)-2,5-diphenyltetrazoliumbromid) Assay	ISO 10993-5:2009,
361.	Biopsy & Surgical Devices (Scalpels, Hemostat, Forcep, Needle Kit, Surgical Blades, Scissors, Suture)	NRU (Neutral Red Uptake)	ISO 10993-5:2009, OECD 129
362.	Biopsy & Surgical Devices (Scalpels, Hemostat, Forcep, Needle Kit, Surgical Blades, Scissors, Suture)	XTT (2,3-bis-(2-methoxy-4-nitro-5-sulfophenyl)-2H-tetrazolium-5-carboxanilide)	ISO 10993-5:2009, OECD 129
363.	Biopsy & Surgical Devices (Scalpels, Hemostat, Forcep, Needle Kit, Surgical Blades, Scissors, Suture)	Cytotoxicity (MEM)	ISO 10993-5:2009
364.	Cannula (Coronary Artery, IV, IV with Safety Clip, Venous, Ventricular, Y Connector Arterial, Introducer Sheath)	MTT (3-(4,5-dimethylthiazol-2-yl)-2,5-diphenyltetrazoliumbromid) Assay	ISO 10993-5:2009,
365.	Cannula (Coronary Artery, IV, IV with Safety Clip, Venous, Ventricular, Y Connector Arterial, Introducer Sheath)	NRU (Neutral Red Uptake)	ISO 10993-5:2009, OECD 129



Quality And Accreditation Institute

Centre for Laboratory Accreditation



Scope of Accreditation

Chemzin Biotox Research Institute Private Limited

1st Floor, Plot no-94, EPIP Ind. Area Phase-1, Jharmajri, Baddi

Solan-174103, Himachal Pradesh, India

QAI/CIA/TL/2026/0188

Valid from: 26 August 2026

Valid until: 25 August 2028

Accreditation Standard: ISO/IEC 17025:2017

Biological Testing			
Sl. No.	Product(s)/Material of Test	Specific Tests Performed	Test Method
	Medical Accessories & Surgical Products		
366.	Cannula (Coronary Artery, IV, IV with Safety Clip, Venous, Ventricular, Y Connector Arterial, Introducer Sheath)	XTT (2,3-bis-(2-methoxy-4-nitro-5-sulfophenyl)-2H-tetrazolium-5-carboxanilide)	ISO 10993-5:2009, OECD 129
367.	Cannula (Coronary Artery, IV, IV with Safety Clip, Venous, Ventricular, Y Connector Arterial, Introducer Sheath)	Cytotoxicity (MEM)	ISO 10993-5:2009
368.	Cardiovascular Devices (Temporary Pacemaker Electrodes, Heart Valves, vascular Grafts, Drug Eluting Bioresorbable cardiac stent system, Coronary Stent, Ureteral Stent, Heart Lung Pack)	MTT (3-(4,5-dimethylthiazol-2-yl)-2,5-diphenyltetrazoliumbromide) Assay	ISO 10993-5:2009,
369.	Cardiovascular Devices (Temporary Pacemaker Electrodes, Heart Valves, vascular Grafts, Drug Eluting Bioresorbable cardiac stent system, Coronary Stent, Ureteral Stent, Heart Lung Pack)	NRU (Neutral Red Uptake)	ISO 10993-5:2009, OECD 129



Quality And Accreditation Institute

Centre for Laboratory Accreditation



Scope of Accreditation

Chemzin Biotox Research Institute Private Limited

1st Floor, Plot no-94, EPIP Ind. Area Phase-1, Jharmajri, Baddi

Solan-174103, Himachal Pradesh, India

QAI/CIA/TL/2026/0188

Valid from: 26 August 2026

Valid until: 25 August 2028

Accreditation Standard: ISO/IEC 17025:2017

Biological Testing			
Sl. No.	Product(s)/Material of Test	Specific Tests Performed	Test Method
	Medical Accessories & Surgical Products		
370.	Cardiovascular Devices (Temporary Pacemaker Electrodes, Heart Valves, vascular Grafts, Drug Eluting Bioresorbable cardiac stent system, Coronary Stent, Ureteral Stent, Heart Lung Pack)	XTT (2,3-bis-(2-methoxy-4-nitro-5-sulfophenyl)-2H-tetrazolium-5-carboxanilide)	ISO 10993-5:2009, OECD 129
371.	Cardiovascular Devices (Temporary Pacemaker Electrodes, Heart Valves, vascular Grafts, Drug Eluting Bioresorbable cardiac stent system, Coronary Stent, Ureteral Stent, Heart Lung Pack)	Cytotoxicity (MEM)	ISO 10993-5:2009
372.	Catheters (Disposable Central Venous, Disposable Electrode Recording, Disposable Thermodilution, Double Lumen Set, Foley Two Way, Hemodialysis, Intravascular, Male, Multiple Lumen, Peritoneal Dialysis, Guide Wires, Urethral, Other Catheters, Double Lumen Hemodialysis Kit)	MTT (3-(4,5-dimethylthiazol-2-yl)-2,5-diphenyltetrazoliumbromid) Assay	ISO 10993-5:2009,



Quality And Accreditation Institute

Centre for Laboratory Accreditation



Scope of Accreditation

Chemzin Biotox Research Institute Private Limited

1st Floor, Plot no-94, EPIP Ind. Area Phase-1, Jharmajri, Baddi

Solan-174103, Himachal Pradesh, India

QAI/CIA/TL/2026/0188

Valid from: 26 August 2026

Valid until: 25 August 2028

Accreditation Standard: ISO/IEC 17025:2017

Biological Testing			
Sl. No.	Product(s)/Material of Test	Specific Tests Performed	Test Method
	Medical Accessories & Surgical Products		
373.	Catheters (Disposable Central Venous, Disposable Electrode Recording, Disposable Thermodilution, Double Lumen Set, Foley Two Way, Hemodialysis, Intravascular, Male, Multiple Lumen, Peritoneal Dialysis, Guide Wires, Urethral, Other Catheters, Double Lumen Hemodialysis Kit)	NRU (Neutral Red Uptake)	ISO 10993-5:2009, OECD 129
374.	Catheters (Disposable Central Venous, Disposable Electrode Recording, Disposable Thermodilution, Double Lumen Set, Foley Two Way, Hemodialysis, Intravascular, Male, Multiple Lumen, Peritoneal Dialysis, Guide Wires, Urethral, Other Catheters, Double Lumen Hemodialysis Kit)	XTT (2,3-bis-(2-methoxy-4-nitro-5-sulfophenyl)-2H-tetrazolium-5-carboxanilide)	ISO 10993-5:2009, OECD 129
375.	Catheters (Disposable Central Venous, Disposable Electrode Recording, Disposable Thermodilution, Double Lumen Set, Foley Two Way,	Cytotoxicity (MEM)	ISO 10993-5:2009

This is annexure to 'Certificate of Accreditation' and does not require any signature.

www.qai.org.in



50 of 76

Quality And Accreditation Institute

Centre for Laboratory Accreditation



Scope of Accreditation

Chemzin Biotox Research Institute Private Limited

1st Floor, Plot no-94, EPIP Ind. Area Phase-1, Jharmajri, Baddi

Solan-174103, Himachal Pradesh, India

QAI/CIA/TL/2026/0188

Valid from: 26 August 2026

Valid until: 25 August 2028

Accreditation Standard: ISO/IEC 17025:2017

Biological Testing			
Sl. No.	Product(s)/Material of Test	Specific Tests Performed	Test Method
	Medical Accessories & Surgical Products		
	Hemodialysis, Intravascular, Male, Multiple Lumen, Peritoneal Dialysis, Guide Wires, Urethral, Other Catheters, Double Lumen Hemodialysis Kit)		
376.	Dental Products (Denture Teeth, Burs, Cements, Filling, Implants, Base Resins, Orthodontic Device, Tooth Brush, Permanent Crown, Braces)	MTT (3-(4,5-dimethylthiazol-2-yl)-2,5-diphenyltetrazoliumbromid) Assay	ISO 10993-5:2009,
377.	Dental Products (Denture Teeth, Burs, Cements, Filling, Implants, Base Resins, Orthodontic Device, Tooth Brush, Permanent Crown, Braces)	NRU (Neutral Red Uptake)	ISO 10993-5:2009, OECD 129
378.	Dental Products (Denture Teeth, Burs, Cements, Filling, Implants, Base Resins, Orthodontic Device, Tooth Brush, Permanent Crown, Braces)	XTT (2,3-bis-(2-methoxy-4-nitro-5-sulfophenyl)-2H-tetrazolium-5-carboxanilide)	ISO 10993-5:2009, OECD 129
379.	Dental Products (Denture Teeth, Burs, Cements, Filling, Implants, Base Resins, Orthodontic	Cytotoxicity (MEM)	ISO 10993-5:2009



Quality And Accreditation Institute

Centre for Laboratory Accreditation



Scope of Accreditation

Chemzin Biotox Research Institute Private Limited

1st Floor, Plot no-94, EPIP Ind. Area Phase-1, Jharmajri, Baddi

Solan-174103, Himachal Pradesh, India

QAI/CIA/TL/2026/0188

Valid from: 26 August 2026

Valid until: 25 August 2028

Accreditation Standard: ISO/IEC 17025:2017

Biological Testing			
Sl. No.	Product(s)/Material of Test	Specific Tests Performed	Test Method
	Medical Accessories & Surgical Products		
	Device, Tooth Brush, Permanent Crown, Braces)		
380.	Disposable & Surface Devices (Electrode Recording Probe, Hypodermic Needles, Infusion Set, Transfusion Set, Face Mask, Surgical Gown, PPE, Gloves, Urine Collection Bag, Hearing aid (Collar Ear Button, Paparella ear ventilation tubes), Hb Test Strips, Barrier Creams, ECG Gels, EEG Gels, EP Paste, Sanitary Pads, Diapers, Blood Collection Bag)	MTT (3-(4,5-dimethylthiazol-2-yl)-2,5-diphenyltetrazoliumbromid) Assay	ISO 10993-5:2009,
381.	Disposable & Surface Devices (Electrode Recording Probe, Hypodermic Needles, Infusion Set, Transfusion Set, Face Mask, Surgical Gown, PPE, Gloves, Urine Collection Bag, Hearing aid (Collar Ear Button, Paparella ear ventilation tubes), Hb Test Strips, Barrier Creams, ECG Gels, EEG Gels, EP Paste, Sanitary	NRU (Neutral Red Uptake)	ISO 10993-5:2009, OECD 129



Quality And Accreditation Institute

Centre for Laboratory Accreditation



Scope of Accreditation

Chemzin Biotox Research Institute Private Limited

1st Floor, Plot no-94, EPIP Ind. Area Phase-1, Jharmajri, Baddi

Solan-174103, Himachal Pradesh, India

QAI/CIA/TL/2026/0188

Valid from: 26 August 2026

Valid until: 25 August 2028

Accreditation Standard: ISO/IEC 17025:2017

Biological Testing			
Sl. No.	Product(s)/Material of Test	Specific Tests Performed	Test Method
	Medical Accessories & Surgical Products		
	Pads, Diapers, Blood Collection Bag)		
382.	Disposable & Surface Devices (Electrode Recording Probe, Hypodermic Needles, Infusion Set, Transfusion Set, Face Mask, Surgical Gown, PPE, Gloves, Urine Collection Bag, Hearing aid (Collar Ear Button, Paparella ear ventilation tubes), Hb Test Strips, Barrier Creams, ECG Gels, EEG Gels, EP Paste, Sanitary Pads, Diapers, Blood Collection Bag)	XTT (2,3-bis-(2-methoxy-4-nitro-5-sulfophenyl)-2H-tetrazolium-5-carboxanilide)	ISO 10993-5:2009,
383.	Disposable & Surface Devices (Electrode Recording Probe, Hypodermic Needles, Infusion Set, Transfusion Set, Face Mask, Surgical Gown, PPE, Gloves, Urine Collection Bag, Hearing aid (Collar Ear Button, Paparella ear ventilation tubes), Hb Test Strips, Barrier Creams, ECG Gels, EEG Gels, EP Paste, Sanitary	Cytotoxicity (MEM)	ISO 10993-5:2009



Quality And Accreditation Institute

Centre for Laboratory Accreditation



Scope of Accreditation

Chemzin Biotox Research Institute Private Limited

1st Floor, Plot no-94, EPIP Ind. Area Phase-1, Jharmajri, Baddi

Solan-174103, Himachal Pradesh, India

QAI/CIA/TL/2026/0188

Valid from: 26 August 2026

Valid until: 25 August 2028

Accreditation Standard: ISO/IEC 17025:2017

Biological Testing			
Sl. No.	Product(s)/Material of Test	Specific Tests Performed	Test Method
	Medical Accessories & Surgical Products		
	Pads, Diapers, Blood Collection Bag)		
384.	Dressing Material (Absorbent Cotton, Wound Surgicals Cotton, Bandages, Wound Surgicals Bandages, Wound Protector, Wound Surgicals Protector, Invo Vac Foam Dressing)	MTT (3-(4,5-dimethylthiazol-2-yl)-2,5-diphenyltetrazoliumbromide) Assay	ISO 10993-5:2009,
385.	Dressing Material (Absorbent Cotton, Wound Surgicals Cotton, Bandages, Wound Surgicals Bandages, Wound Protector, Wound Surgicals Protector, Invo Vac Foam Dressing)	NRU (Neutral Red Uptake)	ISO 10993-5:2009, OECD 129
386.	Dressing Material (Absorbent Cotton, Wound Surgicals Cotton, Bandages, Wound Surgicals Bandages, Wound Protector, Wound Surgicals Protector, Invo Vac Foam Dressing)	XTT (2,3-bis-(2-methoxy-4-nitro-5-sulfophenyl)-2H-tetrazolium-5-carboxanilide)	ISO 10993-5:2009,



Quality And Accreditation Institute

Centre for Laboratory Accreditation



Scope of Accreditation

Chemzin Biotox Research Institute Private Limited

1st Floor, Plot no-94, EPIP Ind. Area Phase-1, Jharmajri, Baddi

Solan-174103, Himachal Pradesh, India

QAI/CIA/TL/2026/0188

Valid from: 26 August 2026

Valid until: 25 August 2028

Accreditation Standard: ISO/IEC 17025:2017

Biological Testing			
Sl. No.	Product(s)/Material of Test	Specific Tests Performed	Test Method
	Medical Accessories & Surgical Products		
387.	Dressing Material (Absorbent Cotton, Wound Surgicals Cotton, Bandages, Wound Surgicals Bandages, Wound Protector, Wound Surgicals Protector, Invo Vac Foam Dressing)	Cytotoxicity (MEM)	ISO 10993-5:2009
388.	Endoscope (Ligation Device, Mucosal Resection, Bronchoscope, Laproscope, Orthroscope, Laryngoscope, Stone Extraction Balloon)	MTT (3-(4,5-dimethylthiazol-2-yl)-2,5-diphenyltetrazoliumbromide) Assay	ISO 10993-5:2009,
389.	Endoscope (Ligation Device, Mucosal Resection, Bronchoscope, Laproscope, Orthroscope, Laryngoscope, Stone Extraction Balloon)	NRU (Neutral Red Uptake)	ISO 10993-5:2009, OECD 129
390.	Endoscope (Ligation Device, Mucosal Resection, Bronchoscope, Laproscope, Orthroscope, Laryngoscope, Stone Extraction Balloon)	XTT (2,3-bis-(2-methoxy-4-nitro-5-sulfophenyl)-2H-tetrazolium-5-carboxanilide)	ISO 10993-5:2009,
391.	Endoscope (Ligation Device, Mucosal Resection,	Cytotoxicity (MEM)	ISO 10993-5:2009



Quality And Accreditation Institute

Centre for Laboratory Accreditation



Scope of Accreditation

Chemzin Biotox Research Institute Private Limited

1st Floor, Plot no-94, EPIP Ind. Area Phase-1, Jharmajri, Baddi

Solan-174103, Himachal Pradesh, India

QAI/CIA/TL/2026/0188

Valid from: 26 August 2026

Valid until: 25 August 2028

Accreditation Standard: ISO/IEC 17025:2017

Biological Testing			
Sl. No.	Product(s)/Material of Test	Specific Tests Performed	Test Method
	Medical Accessories & Surgical Products		
	Bronchoscope, Laproscope, Orthroscope, Laryngoscope, Stone Extraction Balloon)		
392.	Natural Orifice Devices (Natural Rubber Latex Condom, Latex Oral Dam, Intravaginal Devices, Intra uterine devices, Ligation Clips, Digital Thermometer)	MTT (3-(4,5-dimethylthiazol-2-yl)-2,5-diphenyltetrazoliumbromide) Assay	ISO 10993-5:2009,
393.	Natural Orifice Devices (Natural Rubber Latex Condom, Latex Oral Dam, Intravaginal Devices, Intra uterine devices, Ligation Clips, Digital Thermometer)	NRU (Neutral Red Uptake)	ISO 10993-5:2009, OECD 129
394.	Natural Orifice Devices (Natural Rubber Latex Condom, Latex Oral Dam, Intravaginal Devices, Intra uterine devices, Ligation Clips, Digital Thermometer)	XTT (2,3-bis-(2-methoxy-4-nitro-5-sulfophenyl)-2H-tetrazolium-5-carboxanilide)	ISO 10993-5:2009,
395.	Natural Orifice Devices (Natural Rubber Latex Condom, Latex Oral Dam, Intravaginal Devices, Intra uterine devices, Ligation Clips, Digital Thermometer)	Cytotoxicity (MEM)	ISO 10993-5:2009



Quality And Accreditation Institute

Centre for Laboratory Accreditation



Scope of Accreditation

Chemzin Biotox Research Institute Private Limited

1st Floor, Plot no-94, EPIP Ind. Area Phase-1, Jharmajri, Baddi

Solan-174103, Himachal Pradesh, India

QAI/CIA/TL/2026/0188

Valid from: 26 August 2026

Valid until: 25 August 2028

Accreditation Standard: ISO/IEC 17025:2017

Biological Testing			
Sl. No.	Product(s)/Material of Test	Specific Tests Performed	Test Method
	Medical Accessories & Surgical Products		
396.	Ophthalmic Products (Contact Lenses, Solutions, Inserts, Intraocular lenses, others)	MTT (3-(4,5-dimethylthiazol-2-yl)-2,5-diphenyltetrazoliumbromid) Assay	ISO 10993-5:2009,
397.	Ophthalmic Products (Contact Lenses, Solutions, Inserts, Intraocular lenses, others)	NRU (Neutral Red Uptake)	ISO 10993-5:2009, OECD 129
398.	Ophthalmic Products (Contact Lenses, Solutions, Inserts, Intraocular lenses, others)	XTT (2,3-bis-(2-methoxy-4-nitro-5-sulfophenyl)-2H-tetrazolium-5-carboxanilide)	ISO 10993-5:2009,
399.	Ophthalmic Products (Contact Lenses, Solutions, Inserts, Intraocular lenses, others)	Cytotoxicity (MEM)	ISO 10993-5:2009
400.	Orthopedic (Moore's Pin, Pins, Plates, Screws, Small Joints, Wires, Interlocking Nails)	MTT (3-(4,5-dimethylthiazol-2-yl)-2,5-diphenyltetrazoliumbromid) Assay	ISO 10993-5:2009,
401.	Orthopedic (Moore's Pin, Pins, Plates, Screws, Small Joints, Wires, Interlocking Nails)	NRU (Neutral Red Uptake)	ISO 10993-5:2009, OECD 129
402.	Orthopedic (Moore's Pin, Pins, Plates, Screws, Small Joints, Wires, Interlocking Nails)	XTT (2,3-bis-(2-methoxy-4-nitro-5-sulfophenyl)-2H-tetrazolium-5-carboxanilide)	ISO 10993-5:2009,
403.	Orthopedic (Moore's Pin, Pins, Plates, Screws, Small Joints, Wires, Interlocking Nails)	Cytotoxicity (MEM)	ISO 10993-5:2009



Quality And Accreditation Institute

Centre for Laboratory Accreditation



Scope of Accreditation

Chemzin Biotox Research Institute Private Limited

1st Floor, Plot no-94, EPIP Ind. Area Phase-1, Jharmajri, Baddi

Solan-174103, Himachal Pradesh, India

QAI/CIA/TL/2026/0188

Valid from: 26 August 2026

Valid until: 25 August 2028

Accreditation Standard: ISO/IEC 17025:2017

Biological Testing			
Sl. No.	Product(s)/Material of Test	Specific Tests Performed	Test Method
	Medical Accessories & Surgical Products		
404.	Polymers & Plastic Granules (Thermoplastic Rubber, Low Density Polyethylene, High Density Polyethylene, Rubber Products)	MTT (3-(4,5-dimethylthiazol-2-yl)-2,5-diphenyltetrazoliumbromid) Assay	ISO 10993-5:2009,
405.	Polymers & Plastic Granules (Thermoplastic Rubber, Low Density Polyethylene, High Density Polyethylene, Rubber Products)	NRU (Neutral Red Uptake)	ISO 10993-5:2009, OECD 129
406.	Polymers & Plastic Granules (Thermoplastic Rubber, Low Density Polyethylene, High Density Polyethylene, Rubber Products)	XTT (2,3-bis-(2-methoxy-4-nitro-5-sulphophenyl)-2H-tetrazolium-5-carboxanilide)	ISO 10993-5:2009,
407.	Polymers & Plastic Granules (Thermoplastic Rubber, Low Density Polyethylene, High Density Polyethylene, Rubber Products)	Cytotoxicity (MEM)	ISO 10993-5:2009
408.	Respiratory devices (Oxygenator, Tubing & Accessories, Nebulizer Bottles,	MTT (3-(4,5-dimethylthiazol-2-yl)-2,5-diphenyltetrazoliumbromid) Assay	ISO 10993-5:2009,



Quality And Accreditation Institute

Centre for Laboratory Accreditation



Scope of Accreditation

Chemzin Biotox Research Institute Private Limited

1st Floor, Plot no-94, EPIP Ind. Area Phase-1, Jharmajri, Baddi

Solan-174103, Himachal Pradesh, India

QAI/CIA/TL/2026/0188

Valid from: 26 August 2026

Valid until: 25 August 2028

Accreditation Standard: ISO/IEC 17025:2017

Biological Testing			
Sl. No.	Product(s)/Material of Test	Specific Tests Performed	Test Method
	Medical Accessories & Surgical Products		
	Nebulizer Mask, Other Nebulizers, Extra Corporal)		
409.	Respiratory devices (Oxygenator, Tubing & Accessories, Nebulizer Bottles, Nebulizer Mask, Other Nebulizers, Extra Corporal)	NRU (Neutral Red Uptake)	ISO 10993-5:2009, OECD 129
410.	Respiratory devices (Oxygenator, Tubing & Accessories, Nebulizer Bottles, Nebulizer Mask, Other Nebulizers, Extra Corporal)	XTT (2,3-bis-(2-methoxy-4-nitro-5-sulfophenyl)-2H-tetrazolium-5-carboxanilide)	ISO 10993-5:2009,
411.	Respiratory devices (Oxygenator, Tubing & Accessories, Nebulizer Bottles, Nebulizer Mask, Other Nebulizers, Extra Corporal)	Cytotoxicity (MEM)	ISO 10993-5:2009
412.	Syringes & Needles (Syringes with Needles, Flush Syringe, Prefilled Syringe, Insulin Syringe, Hypodermic Syringes, Aspiration Needle, Hypodermic Needles, Injection Needles, IP Needle with Diamond Tip)	MTT (3-(4,5-dimethylthiazol-2-yl)-2,5-diphenyltetrazoliumbromide) Assay	ISO 10993-5:2009,



Quality And Accreditation Institute

Centre for Laboratory Accreditation



Scope of Accreditation

Chemzin Biotox Research Institute Private Limited

1st Floor, Plot no-94, EPIP Ind. Area Phase-1, Jharmajri, Baddi

Solan-174103, Himachal Pradesh, India

QAI/CIA/TL/2026/0188

Valid from: 26 August 2026

Valid until: 25 August 2028

Accreditation Standard: ISO/IEC 17025:2017

Biological Testing			
Sl. No.	Product(s)/Material of Test	Specific Tests Performed	Test Method
	Medical Accessories & Surgical Products		
413.	Syringes & Needles (Syringes with Needles, Flush Syringe, Prefilled Syringe, Insulin Syringe, Hypodermic Syringes, Aspiration Needle, Hypodermic Needles, Injection Needles, IP Needle with Diamond Tip)	NRU (Neutral Red Uptake)	ISO 10993-5:2009, OECD 129
414.	Syringes & Needles (Syringes with Needles, Flush Syringe, Prefilled Syringe, Insulin Syringe, Hypodermic Syringes, Aspiration Needle, Hypodermic Needles, Injection Needles, IP Needle with Diamond Tip)	XTT (2,3-bis-(2-methoxy-4-nitro-5-sulfophenyl)-2H-tetrazolium-5-carboxanilide)	ISO 10993-5:2009,
415.	Syringes & Needles (Syringes with Needles, Flush Syringe, Prefilled Syringe, Insulin Syringe, Hypodermic Syringes, Aspiration Needle, Hypodermic Needles, Injection Needles, IP Needle with Diamond Tip)	Cytotoxicity (MEM)	ISO 10993-5:2009
416.	Tubes (Infant Feeding, Ryles, Endotracheal, Drainage Set, Closed Wound Drainage Tube, Dialysis Tubes & Accessories,	MTT (3-(4,5-dimethylthiazol-2-yl)-2,5-diphenyltetrazoliumbromid) Assay	ISO 10993-5:2009,

This is annexure to 'Certificate of Accreditation' and does not require any signature.

www.qai.org.in



60 of 76

Quality And Accreditation Institute

Centre for Laboratory Accreditation



Scope of Accreditation

Chemzin Biotox Research Institute Private Limited

1st Floor, Plot no-94, EPIP Ind. Area Phase-1, Jharmajri, Baddi

Solan-174103, Himachal Pradesh, India

QAI/CIA/TL/2026/0188

Valid from: 26 August 2026

Valid until: 25 August 2028

Accreditation Standard: ISO/IEC 17025:2017

Biological Testing			
Sl. No.	Product(s)/Material of Test	Specific Tests Performed	Test Method
	Medical Accessories & Surgical Products		
	Transfusion Sets, Solution & Blood Administration Set, Manifolds, 3 Way Stop Cock & Extension Line)		
417.	Tubes (Infant Feeding, Ryles, Endotracheal, Drainage Set, Closed Wound Drainage Tube, Dialysis Tubes & Accessories, Transfusion Sets, Solution & Blood Administration Set, Manifolds, 3 Way Stop Cock & Extension Line)	NRU (Neutral Red Uptake)	ISO 10993-5:2009, OECD 129
418.	Tubes (Infant Feeding, Ryles, Endotracheal, Drainage Set, Closed Wound Drainage Tube, Dialysis Tubes & Accessories, Transfusion Sets, Solution & Blood Administration Set, Manifolds, 3 Way Stop Cock & Extension Line)	XTT (2,3-bis-(2-methoxy-4-nitro-5-sulfophenyl)-2H-tetrazolium-5-carboxanilide)	ISO 10993-5:2009,
419.	Tubes (Infant Feeding, Ryles, Endotracheal, Drainage Set, Closed Wound Drainage Tube, Dialysis Tubes & Accessories, Transfusion Sets, Solution &	Cytotoxicity (MEM)	ISO 10993-5:2009

This is annexure to 'Certificate of Accreditation' and does not require any signature.

www.qai.org.in



61 of 76

Quality And Accreditation Institute

Centre for Laboratory Accreditation



Scope of Accreditation

Chemzin Biotox Research Institute Private Limited

1st Floor, Plot no-94, EPIP Ind. Area Phase-1, Jharmajri, Baddi

Solan-174103, Himachal Pradesh, India

QAI/CIA/TL/2026/0188

Valid from: 26 August 2026

Valid until: 25 August 2028

Accreditation Standard: ISO/IEC 17025:2017

Biological Testing			
Sl. No.	Product(s)/Material of Test	Specific Tests Performed	Test Method
	Medical Accessories & Surgical Products		
	Blood Administration Set, Manifolds, 3 Way Stop Cock & Extension Line)		
420.	Guiding catheters for cardiac catheterization procedures	MTT (3-(4,5-dimethylthiazol-2-yl)-2,5-diphenyltetrazoliumbromid) Assay	ISO 10993-5:2009,
421.	Guiding catheters for cardiac catheterization procedures	NRU (Neutral Red Uptake)	ISO 10993-5:2009, OECD 129
422.	Guiding catheters for cardiac catheterization procedures	XTT (2,3-bis-(2-methoxy-4-nitro-5-sulfophenyl)-2H-tetrazolium-5-carboxanilide)	ISO 10993-5:2009,
423.	Guiding catheters for cardiac catheterization procedures	Cytotoxicity (MEM)	ISO 10993-5:2009
424.	Dilatation catheters (balloon dilatation catheters) for widen narrowed or blocked passages in the body	MTT (3-(4,5-dimethylthiazol-2-yl)-2,5-diphenyltetrazoliumbromid) Assay	ISO 10993-5:2009,
425.	Dilatation catheters (balloon dilatation catheters) for widen narrowed or blocked passages in the body	NRU (Neutral Red Uptake)	ISO 10993-5:2009, OECD 129
426.	Dilatation catheters (balloon dilatation catheters) for widen	XTT (2,3-bis-(2-methoxy-4-nitro-5-sulfophenyl)-2H-tetrazolium-5-carboxanilide)	ISO 10993-5:2009,



Quality And Accreditation Institute

Centre for Laboratory Accreditation



Scope of Accreditation

Chemzin Biotox Research Institute Private Limited

1st Floor, Plot no-94, EPIP Ind. Area Phase-1, Jharmajri, Baddi

Solan-174103, Himachal Pradesh, India

QAI/CIA/TL/2026/0188

Valid from: 26 August 2026

Valid until: 25 August 2028

Accreditation Standard: ISO/IEC 17025:2017

Biological Testing			
Sl. No.	Product(s)/Material of Test	Specific Tests Performed	Test Method
	Medical Accessories & Surgical Products		
	narrowed or blocked passages in the body		
427.	Dilatation catheters (balloon dilatation catheters) for widen narrowed or blocked passages in the body	Cytotoxicity (MEM)	ISO 10993-5:2009
428.	Hemodialysis catheters for provide temporary or long-term access to bloodstream (Dual lumen catheter, Vessel Dilator, Injection caps, Normal syringe 10ml, Medifix, Tunneler, Cotton Gauze Sponge, Scalpel, Introducer Needle, Material Sheet, Surgical Needled Suture)	MTT (3-(4,5-dimethylthiazol-2-yl)-2,5-diphenyltetrazoliumbromid) Assay	ISO 10993-5:2009,
429.	Hemodialysis catheters for provide temporary or long-term access to bloodstream (Dual lumen catheter, Vessel Dilator, Injection caps, Normal syringe 10ml, Medifix, Tunneler, Cotton Gauze Sponge, Scalpel, Introducer Needle, Material Sheet, Surgical Needled Suture)	NRU (Neutral Red Uptake)	ISO 10993-5:2009, OECD 129



Quality And Accreditation Institute

Centre for Laboratory Accreditation



Scope of Accreditation

Chemzin Biotox Research Institute Private Limited

1st Floor, Plot no-94, EPIP Ind. Area Phase-1, Jharmajri, Baddi

Solan-174103, Himachal Pradesh, India

QAI/CIA/TL/2026/0188

Valid from: 26 August 2026

Valid until: 25 August 2028

Accreditation Standard: ISO/IEC 17025:2017

Biological Testing			
Sl. No.	Product(s)/Material of Test	Specific Tests Performed	Test Method
	Medical Accessories & Surgical Products		
430.	Hemodialysis catheters for provide temporary or long-term access to bloodstream (Dual lumen catheter, Vessel Dilator, Injection caps, Normal syringe 10ml, Medifix, Tunneler, Cotton Gauze Sponge, Scalpel, Introducer Needle, Material Sheet, Surgical Needled Suture)	XTT (2,3-bis-(2-methoxy-4-nitro-5-sulfophenyl)-2H-tetrazolium-5-carboxanilide)	ISO 10993-5:2009,
431.	Hemodialysis catheters for provide temporary or long-term access to bloodstream (Dual lumen catheter, Vessel Dilator, Injection caps, Normal syringe 10ml, Medifix, Tunneler, Cotton Gauze Sponge, Scalpel, Introducer Needle, Material Sheet, Surgical Needled Suture)	Cytotoxicity (MEM)	ISO 10993-5:2009
432.	Dilatation catheters– SC (balloon dilatation catheters) for widen narrowed or blocked passages in the body	MTT (3-(4,5-dimethylthiazol-2-yl)-2,5-diphenyltetrazoliumbromid) Assay	ISO 10993-5:2009,
433.	Dilatation catheters– SC (balloon dilatation catheters) for	NRU (Neutral Red Uptake)	ISO 10993-5:2009, OECD 129



Quality And Accreditation Institute

Centre for Laboratory Accreditation



Scope of Accreditation

Chemzin Biotox Research Institute Private Limited

1st Floor, Plot no-94, EPIP Ind. Area Phase-1, Jharmajri, Baddi

Solan-174103, Himachal Pradesh, India

QAI/CIA/TL/2026/0188

Valid from: 26 August 2026

Valid until: 25 August 2028

Accreditation Standard: ISO/IEC 17025:2017

Biological Testing			
Sl. No.	Product(s)/Material of Test	Specific Tests Performed	Test Method
	Medical Accessories & Surgical Products		
	widen narrowed or blocked passages in the body		
434.	Dilatation catheters– SC (balloon dilatation catheters) for widen narrowed or blocked passages in the body	XTT (2,3-bis-(2-methoxy-4-nitro-5-sulphophenyl)-2H-tetrazolium-5-carboxanilide)	ISO 10993-5:2009
435.	Dilatation catheters– SC (balloon dilatation catheters) for widen narrowed or blocked passages in the body	Cytotoxicity (MEM)	ISO 10993-5:2009
436.	Pharmaceuticals, Biopharmaceuticals, Nutraceuticals and plant products	Acute oral Toxicity	ISO 10993-5:2009, OECD 423
437.	Pharmaceuticals, Biopharmaceuticals, Nutraceuticals and plant products	Acute Systemic /Sub-Acute Systemic /Chronic/ Sub-Chronic Toxicity	ISO 10993-5:2009



Quality And Accreditation Institute

Centre for Laboratory Accreditation



Scope of Accreditation

Chemzin Biotox Research Institute Private Limited

1st Floor, Plot no-94, EPIP Ind. Area Phase-1, Jharmajri, Baddi

Solan-174103, Himachal Pradesh, India

QAI/CIA/TL/2026/0188

Valid from: 26 August 2026

Valid until: 25 August 2028

Accreditation Standard: ISO/IEC 17025:2017

Biological Discipline			
Sl. No.	Product(s)/Material of Test	Specific Tests Performed	Test Method
	Cosmetics & Essential oils		
1.	Moisturizing cream, acne-control cream, aftershave cream, anti-acne cream, anti-aging cream, anti-pigmentation cream, baby cream, BB/CC cream, cold cream, concealer cream, D-tanning cream, eye cream, fairness/brightening cream, foot cream, foundation cream, herbal/natural cream, men's cream, night cream, oil control cream, pore-minimizing cream, primer cream, saving cream, sunscreen cream, tinted moisturizer cream, and wrinkle-reducing cream.	MTT (3-(4,5-dimethylthiazol-2-yl)-2,5-diphenyltetrazoliumbromide) Assay	ISO 10993-Part 5:2009
2.	Moisturizing cream, acne-control cream, aftershave cream, anti-acne cream, anti-aging cream, anti-pigmentation cream, baby cream, BB/CC cream, cold cream, concealer cream, D-tanning cream, eye cream, fairness/brightening cream, foot cream, foundation	NRU (Neutral Red Uptake)	I ISO 10993-Part 5:2009/ OECD 129



Quality And Accreditation Institute

Centre for Laboratory Accreditation



Scope of Accreditation

Chemzin Biotox Research Institute Private Limited

1st Floor, Plot no-94, EPIP Ind. Area Phase-1, Jharmajri, Baddi

Solan-174103, Himachal Pradesh, India

QAI/CIA/TL/2026/0188

Valid from: 26 August 2026

Valid until: 25 August 2028

Accreditation Standard: ISO/IEC 17025:2017

Biological Discipline			
Sl. No.	Product(s)/Material of Test	Specific Tests Performed	Test Method
	Cosmetics & Essential oils		
	cream, herbal/natural cream, men's cream, night cream, oil control cream, pore-minimizing cream, primer cream, saving cream, sunscreen cream, tinted moisturizer cream, and wrinkle-reducing cream.		
3.	Moisturizing cream, acne-control cream, aftershave cream, anti-acne cream, anti-aging cream, anti-pigmentation cream, baby cream, BB/CC cream, cold cream, concealer cream, D-tanning cream, eye cream, fairness/brightening cream, foot cream, foundation cream, herbal/natural cream, men's cream, night cream, oil control cream, pore-minimizing cream, primer cream, saving cream, sunscreen cream, tinted moisturizer cream, and wrinkle-reducing cream.	XTT (2,3-bis-(2-methoxy-4-nitro-5-sulfophenyl)-2H-tetrazolium-5-carboxanilide)	ISO 10993-Part 5:2009
4.	Moisturizing cream, acne-control cream, aftershave	Cytotoxicity (MEM)	ISO 10993-Part 5:2009



Quality And Accreditation Institute

Centre for Laboratory Accreditation



Scope of Accreditation

Chemzin Biotox Research Institute Private Limited

1st Floor, Plot no-94, EPIP Ind. Area Phase-1, Jharmajri, Baddi

Solan-174103, Himachal Pradesh, India

QAI/CIA/TL/2026/0188

Valid from: 26 August 2026

Valid until: 25 August 2028

Accreditation Standard: ISO/IEC 17025:2017

Biological Discipline			
Sl. No.	Product(s)/Material of Test	Specific Tests Performed	Test Method
	Cosmetics & Essential oils		
	cream, anti-acne cream, anti-aging cream, anti-pigmentation cream, baby cream, BB/CC cream, cold cream, concealer cream, D-tanning cream, eye cream, fairness/brightening cream, foot cream, foundation cream, herbal/natural cream, men's cream, night cream, oil control cream, pore-minimizing cream, primer cream, saving cream, sunscreen cream, tinted moisturizer cream, and wrinkle-reducing cream.		
5.	After-shave gel, analgesic gel, anti-acne gel, antifungal gel, antiseptic gel, benzoyl peroxide gel, chlorhexidine gel, clindamycin gel, cooling gel, cooling menthol gel, diclofenac gel, eye gel, fluoride dental gel, hair gel, herbal gel, hyaluronic acid gel, ketoprofen gel, lidocaine gel, metronidazole gel, niacinamide gel, povidone-	MTT (3-(4,5-dimethylthiazol-2-yl)-2,5-diphenyltetrazoliumbromide) Assay	ISO 10993-Part 5:2009



Quality And Accreditation Institute

Centre for Laboratory Accreditation



Scope of Accreditation

Chemzin Biotox Research Institute Private Limited

1st Floor, Plot no-94, EPIP Ind. Area Phase-1, Jharmajri, Baddi

Solan-174103, Himachal Pradesh, India

QAI/CIA/TL/2026/0188

Valid from: 26 August 2026

Valid until: 25 August 2028

Accreditation Standard: ISO/IEC 17025:2017

Biological Discipline			
Sl. No.	Product(s)/Material of Test	Specific Tests Performed	Test Method
	Cosmetics & Essential oils		
	iodine gel, salicylic acid gel, sunburn relief gel, sunscreen gel, turmeric gel, vitamin E gel, whitening gel, and aloe vera gel, Body shimmer gel and body wash gels		
6.	After-shave gel, analgesic gel, anti-acne gel, antifungal gel, antiseptic gel, benzoyl peroxide gel, chlorhexidine gel, clindamycin gel, cooling gel, cooling menthol gel, diclofenac gel, eye gel, fluoride dental gel, hair gel, herbal gel, hyaluronic acid gel, ketoprofen gel, lidocaine gel, metronidazole gel, niacinamide gel, povidone-iodine gel, salicylic acid gel, sunburn relief gel, sunscreen gel, turmeric gel, vitamin E gel, whitening gel, and aloe vera gel, Body shimmer gel and body wash gels	NRU (Neutral Red Uptake)	ISO 10993-Part 5:2009/OECD 129



Quality And Accreditation Institute

Centre for Laboratory Accreditation



Scope of Accreditation

Chemzin Biotox Research Institute Private Limited

1st Floor, Plot no-94, EPIP Ind. Area Phase-1, Jharmajri, Baddi

Solan-174103, Himachal Pradesh, India

QAI/CIA/TL/2026/0188

Valid from: 26 August 2026

Valid until: 25 August 2028

Accreditation Standard: ISO/IEC 17025:2017

Biological Discipline			
Sl. No.	Product(s)/Material of Test	Specific Tests Performed	Test Method
	Cosmetics & Essential oils		
7.	After-shave gel, analgesic gel, anti-acne gel, antifungal gel, antiseptic gel, benzoyl peroxide gel, chlorhexidine gel, clindamycin gel, cooling gel, cooling menthol gel, diclofenac gel, eye gel, fluoride dental gel, hair gel, herbal gel, hyaluronic acid gel, ketoprofen gel, lidocaine gel, metronidazole gel, niacinamide gel, povidone-iodine gel, salicylic acid gel, sunburn relief gel, sunscreen gel, turmeric gel, vitamin E gel, whitening gel, and aloe vera gel, Body shimmer gel and body wash gels	XTT (2,3-bis-(2-methoxy-4-nitro-5-sulfophenyl)-2H-tetrazolium-5-carboxanilide)	ISO 10993-Part 5:2009
8.	After-shave gel, analgesic gel, anti-acne gel, antifungal gel, antiseptic gel, benzoyl peroxide gel, chlorhexidine gel, clindamycin gel, cooling gel, cooling menthol gel, diclofenac gel, eye gel, fluoride dental gel, hair gel, herbal gel, hyaluronic	Cytotoxicity (MEM)	ISO 10993-Part 5:2009



Quality And Accreditation Institute

Centre for Laboratory Accreditation



Scope of Accreditation

Chemzin Biotox Research Institute Private Limited

1st Floor, Plot no-94, EPIP Ind. Area Phase-1, Jharmajri, Baddi

Solan-174103, Himachal Pradesh, India

QAI/CIA/TL/2026/0188

Valid from: 26 August 2026

Valid until: 25 August 2028

Accreditation Standard: ISO/IEC 17025:2017

Biological Discipline			
Sl. No.	Product(s)/Material of Test	Specific Tests Performed	Test Method
	Cosmetics & Essential oils		
	acid gel, ketoprofen gel, lidocaine gel, metronidazole gel, niacinamide gel, povidone-iodine gel, salicylic acid gel, sunburn relief gel, sunscreen gel, turmeric gel, vitamin E gel, whitening gel, and aloe vera gel, Body shimmer gel and body wash gels		
9.	After-shave lotion, after-sun soothing lotion, anti-aging lotion, brightening/fairness lotion, deep hydration lotion, firming/anti-cellulite lotion, moisturizing lotion, oil-control/mattifying lotion, sunscreen lotion, and whitening body lotion.	MTT (3-(4,5-dimethylthiazol-2-yl)-2,5-diphenyltetrazoliumbromide) Assay	ISO 10993-Part 5:2009
10.	After-shave lotion, after-sun soothing lotion, anti-aging lotion, brightening/fairness lotion, deep hydration lotion, firming/anti-cellulite lotion, moisturizing lotion, oil-control/mattifying lotion,	NRU (Neutral Red Uptake)	ISO 10993-Part 5:2009/OECD 129



Quality And Accreditation Institute

Centre for Laboratory Accreditation



Scope of Accreditation

Chemzin Biotox Research Institute Private Limited

1st Floor, Plot no-94, EPIP Ind. Area Phase-1, Jharmajri, Baddi

Solan-174103, Himachal Pradesh, India

QAI/CIA/TL/2026/0188

Valid from: 26 August 2026

Valid until: 25 August 2028

Accreditation Standard: ISO/IEC 17025:2017

Biological Discipline			
Sl. No.	Product(s)/Material of Test	Specific Tests Performed	Test Method
	Cosmetics & Essential oils		
	sunscreen lotion, and whitening body lotion		
11.	After-shave lotion, after-sun soothing lotion, anti-aging lotion, brightening/fairness lotion, deep hydration lotion, firming/anti-cellulite lotion, moisturizing lotion, oil-control/mattifying lotion, sunscreen lotion, and whitening body lotion	XTT (2,3-bis-(2-methoxy-4-nitro-5-sulfophenyl)-2H-tetrazolium-5-carboxanilide)	ISO 10993-Part 5:2009
12.	After-shave lotion, after-sun soothing lotion, anti-aging lotion, brightening/fairness lotion, deep hydration lotion, firming/anti-cellulite lotion, moisturizing lotion, oil-control/mattifying lotion, sunscreen lotion, and whitening body lotion	Cytotoxicity (MEM)	ISO 10993-Part 5:2009
13.	Aloe vera serum, argan oil serum, coenzyme Q10 serum, collagen serum, face serum, green tea extract serum, hyaluronic acid serum,	MTT (3-(4,5-dimethylthiazol-2-yl)-2,5-diphenyltetrazoliumbromide) Assay	ISO 10993-Part 5:2009



Quality And Accreditation Institute

Centre for Laboratory Accreditation



Scope of Accreditation

Chemzin Biotox Research Institute Private Limited

1st Floor, Plot no-94, EPIP Ind. Area Phase-1, Jharmajri, Baddi

Solan-174103, Himachal Pradesh, India

QAI/CIA/TL/2026/0188

Valid from: 26 August 2026

Valid until: 25 August 2028

Accreditation Standard: ISO/IEC 17025:2017

Biological Discipline			
Sl. No.	Product(s)/Material of Test	Specific Tests Performed	Test Method
	Cosmetics & Essential oils		
	niacinamide serum, peptide serum, placenta extract serum, retinol serum, snail mucin serum, tea tree serum, vitamin E serum, ginseng extract serum, herbal serum, vitamin C serum, herbal extract serum, and aloe vera serum		
14.	Aloe vera serum, argan oil serum, coenzyme Q10 serum, collagen serum, face serum, green tea extract serum, hyaluronic acid serum, niacinamide serum, peptide serum, placenta extract serum, retinol serum, snail mucin serum, tea tree serum, vitamin E serum, ginseng extract serum, herbal serum, vitamin C serum, herbal extract serum, and aloe vera serum	NRU (Neutral Red Uptake)	ISO 10993-Part 5:2009/OECD 129
15.	Aloe vera serum, argan oil serum, coenzyme Q10 serum, collagen serum, face serum, green tea extract serum,	XTT (2,3-bis-(2-methoxy-4-nitro-5-sulfophenyl)-2H-tetrazolium-5-carboxanilide)	ISO 10993-Part 5:2009



Quality And Accreditation Institute

Centre for Laboratory Accreditation



Scope of Accreditation

Chemzin Biotox Research Institute Private Limited

1st Floor, Plot no-94, EPIP Ind. Area Phase-1, Jharmajri, Baddi

Solan-174103, Himachal Pradesh, India

QAI/CIA/TL/2026/0188

Valid from: 26 August 2026

Valid until: 25 August 2028

Accreditation Standard: ISO/IEC 17025:2017

Biological Discipline			
Sl. No.	Product(s)/Material of Test	Specific Tests Performed	Test Method
	Cosmetics & Essential oils		
	hyaluronic acid serum, niacinamide serum, peptide serum, placenta extract serum, retinol serum, snail mucin serum, tea tree serum, vitamin E serum, ginseng extract serum, herbal serum, vitamin C serum, herbal extract serum, and aloe vera serum		
16.	Aloe vera serum, argan oil serum, coenzyme Q10 serum, collagen serum, face serum, green tea extract serum, hyaluronic acid serum, niacinamide serum, peptide serum, placenta extract serum, retinol serum, snail mucin serum, tea tree serum, vitamin E serum, ginseng extract serum, herbal serum, vitamin C serum, herbal extract serum, and aloe vera serum	Cytotoxicity (MEM)	ISO 10993-Part 5:2009
17.	Saving foam	MTT (3-(4,5-dimethylthiazol-2-yl)-2,5-diphenyltetrazoliumbromid) Assay	ISO 10993-Part 5:2009



Quality And Accreditation Institute

Centre for Laboratory Accreditation



Scope of Accreditation

Chemzin Biotox Research Institute Private Limited

1st Floor, Plot no-94, EPIP Ind. Area Phase-1, Jharmajri, Baddi

Solan-174103, Himachal Pradesh, India

QAI/CIA/TL/2026/0188

Valid from: 26 August 2026

Valid until: 25 August 2028

Accreditation Standard: ISO/IEC 17025:2017

Biological Discipline			
Sl. No.	Product(s)/Material of Test	Specific Tests Performed	Test Method
	Cosmetics & Essential oils		
18.	Saving foam	NRU (Neutral Red Uptake)	ISO 10993-Part 5:2009
19.	Saving foam	XTT (2,3-bis-(2-methoxy-4-nitro-5-sulfophenyl)-2H-tetrazolium-5-carboxanilide)	ISO 10993-Part 5:2009
20.	Saving foam	Cytotoxicity (MEM)	ISO 10993-Part 5:2009
21.	Aloe Vera Ointment, Calendula Ointment, Vitamin E Ointment, Retinol Ointment, Niacinamide Ointment, Chamomile Ointment, Herbal Extract Ointment, Coenzyme Q10 Ointment, Argan Oil Ointment, Snail Mucin Ointment, Shea Butter Ointment, Zinc Oxide Ointment, Hydrocortisone Ointment, Peptide Ointment, Collagen Ointment.	MTT (3-(4,5-dimethylthiazol-2-yl)-2,5-diphenyltetrazoliumbromide) Assay	ISO 10993-Part 5:2009
22.	Aloe Vera Ointment, Calendula Ointment, Vitamin E Ointment, Retinol Ointment, Niacinamide Ointment, Chamomile Ointment, Herbal Extract Ointment, Coenzyme Q10 Ointment, Argan Oil Ointment,	NRU (Neutral Red Uptake)	ISO 10993-Part 5:2009/OECD 129



Quality And Accreditation Institute

Centre for Laboratory Accreditation



Scope of Accreditation

Chemzin Biotox Research Institute Private Limited

1st Floor, Plot no-94, EPIP Ind. Area Phase-1, Jharmajri, Baddi

Solan-174103, Himachal Pradesh, India

QAI/CIA/TL/2026/0188

Valid from: 26 August 2026

Valid until: 25 August 2028

Accreditation Standard: ISO/IEC 17025:2017

Biological Discipline			
Sl. No.	Product(s)/Material of Test	Specific Tests Performed	Test Method
	Cosmetics & Essential oils		
	Snail Mucin Ointment, Shea Butter Ointment, Zinc Oxide Ointment, Hydrocortisone Ointment, Peptide Ointment, Collagen Ointment.		
23.	Aloe Vera Ointment, Calendula Ointment, Vitamin E Ointment, Retinol Ointment, Niacinamide Ointment, Chamomile Ointment, Herbal Extract Ointment, Coenzyme Q10 Ointment, Argan Oil Ointment, Snail Mucin Ointment, Shea Butter Ointment,	XTT (2,3-bis-(2-methoxy-4-nitro-5-sulfophenyl)-2H-tetrazolium-5-carboxanilide)	ISO 10993-Part 5:2009
24.	Hydrocortisone Ointment, Peptide Ointment, Collagen Ointment.	Cytotoxicity (MEM)	ISO 10993-Part 5:2009

