Accredited Laboratory

A2LA has accredited

MDR LABORATORIES PRIVATE LIMITED

Chennai, INDIA

for technical competence in the field of

Biological Testing

This laboratory is accredited in accordance with the recognized International Standard ISO/IEC 17025:2017 *General requirements for the competence of testing and calibration laboratories*. This laboratory also meets the A2LA R256- Specific Requirements. This accreditation demonstrates technical competence for a defined scope and the operation of a laboratory quality management system
(*refer to joint ISO-ILAC-IAF Communiqué dated April 2017*).

Presented this 7th day of April 2026.

Mr. Trace McInturff, Vice President, Accreditation Services
For the Accreditation Council
Certificate Number 7649.01
Valid to March 31, 2028

For the tests to which this accreditation applies, please refer to the laboratory's Biological Scope of Accreditation.

SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

MDR LABORATORIES PRIVATE LIMITED
444 Gokulam Street Mathur
Chennai, INDIA 600068
Parthiban Natarajan Phone: +91-9840875072

BIOLOGICAL

Valid To: March 31, 2028 Certificate Number: 7649.01

In recognition of the successful completion of the A2LA evaluation process, (including an assessment of the organization's compliance with A2LA's R256 Specific Requirements and with U.S. FDA Good Laboratory Practice (GLP) Regulations per 21 CFR Part 58[1]), accreditation is granted to this laboratory to perform the following tests on medical devices:

FDA Recognition Number	Test Name	Standard Method
2-245	MEM Elution Cytotoxicity	ISO 10993-5: Third Edition 2009-06-01, Biological Evaluation of Medical Devices -Part 5: Tests for *In Vitro* Cytotoxicity.
2-248; 2-250	Direct and Indirect Hemolysis	ISO 10993-4: Third Edition 2017-04, Biological Evaluation of Medical Devices - Part 4: Selection of Tests for Interactions with Blood. ASTM F756-17: Standard Practice for Assessment of Hemolytic Properties of Materials.
2-296; 2-256	Guinea Pig Maximization Sensitization	ISO 10993-10 Fourth Edition 2021-11 Biological Evaluation of Medical Devices - Part 10: Tests for skin sensitization. ASTM F720-17: Standard Practice for Testing Guinea Pigs for Contact Allergens: Guinea Pig Maximization Test.
2-291	Intracutaneous Reactivity Irritation Dermal Irritation	ISO 10993-23 First Edition 2021-01. Biological Evaluation of Medical Devices - Part 23: Tests for Irritation.
2-255	Acute Systemic Toxicity	ISO 10993-11: Third Edition 2017-09, Biological Evaluation of Medical Devices - Part 11: Tests for Systemic Toxicity.
2-289	Sample preparation for all test types	ISO 10993-12: Fifth Edition 2021-01, Biological Evaluation of Medical Devices - Part 12: Sample Preparation and Reference Materials.

[1]Assessment to the *U.S. FDA GLP (Good Laboratory Practice) Regulations 21CFR58* does not imply acceptance by the FDA.

5202 Presidents Court, Suite 220 | Frederick, MD 21703-8398 | Phone: 301 644 3248 | Fax: 240 454 9449 | www.A2LA.org

In recognition of the successful completion of the A2LA evaluation process, accreditation is granted to this laboratory to perform the following tests on medical devices in conformance with applicable U.S. FDA Good Laboratory Practice (GLP) Code of Federal Regulations Title 21-part 58 (21CFR58)[1] requirements.

Test Name	Standard Method[1]
Tests for local effects after implantation	ISO 10993-6: Third Edition 2016-12-01, Biological evaluation of medical devices - Part 6: Tests for local effects after implantation
Tests for genotoxicity	ISO 10993-3: Third Edition 2014-10-01, Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity

CHEMICAL

In recognition of the successful completion of the A2LA evaluation process, accreditation is granted to this laboratory to perform the following tests on medical devices, in conformance with applicable U.S. FDA Good Laboratory Practice (GLP) Code of Federal Regulations Title 21-part 58 (21CFR58)[1] requirements.

Test Name	Standard Method[1]
Extraction	ISO 10993-12: Fifth Edition 2021-01, Biological Evaluation of Medical Devices - Part 12: Sample Preparation and Reference Materials.
Elemental Scan by Inductively Coupled Plasma / Mass Spectrometry (ICP/AES)	ISO 10993-18: Fourth Edition 2020-01, Biological evaluation of medical devices — Part 18: Chemical characterization of medical device materials within a risk management process.
Screening of Residual Solvent (VOC) Headspace by Gas Chromatography / Mass Spectrometry (HSGC/MS)	ISO 10993-18: Fourth Edition 2020-01, Biological evaluation of medical devices — Part 18: Chemical characterization of medical device materials within a risk management process.
Screening of Non-Volatile Compounds by Ultra Performance Liquid Chromatography / Mass Spectrometry (UPLC/MS)	ISO 10993-18: Fourth Edition 2020-01, Biological evaluation of medical devices — Part 18: Chemical characterization of medical device materials within a risk management process.
Screening of Semi-Volatile and Volatile Compounds by Direction Injection Gas Chromatography / Mass Spectrometry (GC/MS)	ISO 10993-18: Fourth Edition 2020-01, Biological evaluation of medical devices — Part 18: Chemical characterization of medical device materials within a risk management process.

[1]Assessment to the *U.S. FDA GLP (Good Laboratory Practice) Regulations 21CFR58* does not imply acceptance by the FDA.