SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

ELEMENT MATERIALS TECHNOLOGY BEND, LLC.
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CHEMICAL

Valid To: February 29, 2028 Certificate Number: 7138.01

In recognition of the successful completion of the A2LA evaluation process, accreditation is granted to this laboratory to perform the following test methods on extractable and leachable test solutions obtained from implantable and non-implantable medical devices, components, plastics used for container closure systems for packaging human drugs and biologics, plastic immediate packaging materials, pharmaceutical packaging and delivery systems, plastic components and systems used to manufacture drug products, polymers, thermoplastics, elastomers, glass, metal, drug products, organic and inorganic compounds:

| Test(s) / Technology | Test Method | Reference |
|---|---|---|
| Chemical Characterization (Identification and Quantification) of Compounds Derived from Extractables and Leachables Studies using Gas Chromatography / Mass Spectrometry (GC-MS/FID) | VRTM 409 | ISO 10993-18 (Modified – only performing analytical testing) |
| Chemical Characterization (Identification and Quantification) of Compounds Derived from Extractables and Leachables Studies using Headspace Gas Chromatography / Mass Spectrometry (Headspace-GC-MS/FID) | VRTM 1008 | ISO 10993-18 (Modified – only performing analytical testing) |
| Chemical Characterization (Identification and Quantification) of Compounds Derived from Extractables and Leachables Studies using High Performance Liquid Chromatography / Mass Spectrometry (HPLC-UV-MS) | VRTM 119 | ISO 10993-18 (Modified – only performing analytical testing) |
| Chemical Characterization (Identification and Quantification) of Compounds Derived from Extractables and Leachables Studies using Inductively Coupled Plasma / Mass Spectrometry (ICP-MS) | VRTM 1101 | ISO 10993-18 (Modified – only performing analytical testing) |

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# Accredited Laboratory

A2LA has accredited

## ELEMENT MATERIALS TECHNOLOGY BEND LLC.

*Bend, OR*

for technical competence in the field of

## Chemical 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 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 16th day of March 2026.

Mr. Trace McInturff Vice President, Accreditation Services
For the Accreditation Council
Certificate Number 7138.01
Valid to February 29th, 2028

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

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