

ASCA-Accredited Testing Laboratories

This page lists ASCA-accredited testing laboratories and their respective scopes of accreditation.

Notes:

- Testing laboratories who wish to participate in ASCA should demonstrate that they have been accredited by an ASCA-recognized accreditation body to the currently FDA-recognized versions of the standards and test methods included in ASCA. Please check the Recognized Consensus Standards database for the currently recognized versions.
- Some FDA-recognized consensus standards included in ASCA have an identical U.S. adoption (for example, IEC 60601-2-47, ANSI/AAMI/IEC 60601-2-47). If a testing laboratory has an international (e.g., IEC, ISO) version of a standard in their scope of ASCA Accreditation, any identical US adoption associated with the FDA Recognition number is also considered included in the testing laboratory's scope. For example, if IEC 60601-2-47 with FDA Recognition number 3-155 is listed in a testing laboratory's scope of ASCA Accreditation, testing to the associated ANSI AAMI IEC version is also acceptable even if it is not explicitly listed in the testing lab's scope.
- Some FDA-recognized international consensus standards (e.g., IEC, ISO) included in ASCA are recognized specifically with U.S. national differences applied (e.g., IEC 60601-1, IEC 61010-1). When U.S. national differences are applied to the international versions, they are considered equivalent to the corresponding U.S. adoptions of those standards (e.g., ANSI AAMI ES60601-1, ANSI UL 61010-1). For testing laboratories listed below with such standards in their scope, both the US adoptions and the international versions of the standards are considered as part of their scope of *ASCA Accreditation*.
- For a list of testing laboratories with Withdrawn ASCA Accreditation, see [here](#)⁶

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[CFR Title 21](#)¹⁸ [Radiation-Emitting Products](#)¹⁹ [X-Ray Assembler](#)²⁰ [Medsun Reports](#)²¹ [CLIA](#)²² [TPLC](#)²³

Test Lab: Eurofins Biolab Srl [TL-95]

Accreditation Status: Accreditation Granted - Start Date: 04/04/2023

Accreditation Body Organization Name: [A2LA](#)

Test Lab Primary Contact: Francesca Salvatori, dg_cit005_infomedicaldevice@bpt.eurofinseu.com, Via Bruno Buozzi, 2 20055 VIMODRONE (MI) VIMODRONE IT

Scope of ASCA Accreditation

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Status	Status Date	Category	Biocompatibility Test Method	Recognition Number	Standards Development Organization	Standard Designation Number and Date	Title	Exclusions
Accreditation Granted	04/04/2023	Biocompatibility	Sample preparation for all test types	2-289	ISO	10993-12 Fifth edition 2021-01	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials ²⁴	
Accreditation Granted	04/04/2023	Biocompatibility	MEM Elution Cytotoxicity	2-245	ISO	10993-5 Third edition 2009-06-01	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity ²⁵	

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