



[FDA Home](#)³ [Medical Devices](#)⁴ [Databases](#)⁵

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*.
- Labs listed below with a status of "FDA Initiated Withdrawal" have had their ASCA Accreditation withdrawn as a result of failing to meet the requirements of the ASCA Program as detailed in Section 514(d) of the FD&C Act and the relevant ASCA guidance documents. For some labs listed with a status of "FDA Initiated Withdrawal," the FDA has identified data integrity concerns with testing conducted by the testing laboratory and submitted to the agency in premarket submissions.
- Labs listed below with a status of "Voluntarily Withdrawn" have requested that their ASCA Accreditation be withdrawn voluntarily. This is often due to business decisions (e.g. closing of or moving the laboratory location, limited laboratory services, etc.).

[Learn more...](#)⁶

Search ASCA-Accredited Testing Laboratories

Search

▲ ▼ Arrow buttons can be used to sort the table by each column heading.



⁷ [510\(k\)](#)⁸ [DeNovo](#)⁹ [Registration & Listing](#)¹⁰ [Adverse Events](#)¹¹ [Recalls](#)¹² [PMA](#)¹³ [HDE](#)¹⁴ [Classification](#)¹⁵ [Standards](#)¹⁶
[CFR Title 21](#)¹⁷ [Radiation-Emitting Products](#)¹⁸ [X-Ray Assembler](#)¹⁹ [Medsun Reports](#)²⁰ [CLIA](#)²¹ [TPLC](#)²²

Test Lab: Element Materials Technology Warwick Ltd 4 Hull [TL-167]

Accreditation Status: Accreditation Granted - Start Date: 10/03/2025

Accreditation Body Organization Name: [A2LA](#)

Test Lab Primary Contact: Neil Roche, neil.roche@element.com, Unit E, South Orbital Trading Park Hedon Road Hull, East Yorkshire GB HU9 1NJ

Scope of ASCA Accreditation

[Return to list of Testing Labs](#)

Status	Status Date	Category	Biocompatibility Test Method	Recognition Number	Standards Development Organization	Standard Designation Number and Date	Title	Exclusions
Accreditation Granted	10/03/2025	Basic safety and essential performance		19-36	IEC	60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests ²³	
Accreditation Granted	10/03/2025	Basic safety and essential performance		19-38	IEC	60601-1-11 Edition 2.1 2020-07 CONSOLIDATED VERSION	Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment ²⁴	
Accreditation Granted	10/03/2025	Basic safety and essential performance		19-39	IEC	60601-1-12 Edition 1.1 2020-07 CONSOLIDATED VERSION	Medical electrical equipment - Part 1-12: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment ²⁵	
Accreditation Granted	10/03/2025	Basic safety and essential performance		19-46	ANSI, AAMI	ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021]	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD) [Including Amendment 2 (2021)] ²⁶	
Accreditation Granted	10/03/2025	Basic safety and essential performance		19-49	IEC	60601-1 Edition 3.2 2020-08 CONSOLIDATED VERSION	Medical electrical equipment - Part 1: General requirements - Note: This standard is recognized with relevant US national differences applied, see references #1 and #2 in the Relevant FDA Guidance and/or Supportive Publication section below. ²⁷	
Accreditation Granted	10/03/2025	Basic safety and essential performance		5-131	IEC	60601-1-8 Edition 2.2 2020-07 CONSOLIDATED VERSION	Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems ²⁸	
Accreditation Granted	10/03/2025	Basic safety and essential performance		5-132	IEC	60601-1-6 Edition 3.2 2020-07 CONSOLIDATED VERSION	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability ²⁹	

Scope History

Action Type	ASCA Status	Effective Start Date	Biocompatibility Test Method	Recognition Number	Designation Number	Exclusions
-------------	-------------	----------------------	------------------------------	--------------------	--------------------	------------

Links on this page:

1. <http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain>
2. <http://www.addthis.com/bookmark.php>
3. <https://www.fda.gov/>
4. <https://www.fda.gov/Medical-Devices>
5. <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases>
6. <https://www.fda.gov/medical-devices/standards-and-conformity-assessment-program/asca-accredited-testing-laboratories>
7. </scripts/cdrh/devicesatfda/index.cfm>
8. </scripts/cdrh/cfdocs/cfPMN/pmn.cfm>
9. </scripts/cdrh/cfdocs/cfpmn/denovo.cfm>
10. </scripts/cdrh/cfdocs/cfRL/rl.cfm>
11. </scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfm>
12. </scripts/cdrh/cfdocs/cfRES/res.cfm>
13. </scripts/cdrh/cfdocs/cfPMA/pma.cfm>
14. </scripts/cdrh/cfdocs/cfHDE/hde.cfm>
15. </scripts/cdrh/cfdocs/cfPCD/classification.cfm>
16. </scripts/cdrh/cfdocs/cfStandards/search.cfm>
17. </scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm>
18. /scripts/cdrh/cfdocs/cfPCD_RH/classification.cfm
19. </scripts/cdrh/cfdocs/cfAssem/assembler.cfm>
20. </scripts/cdrh/cfdocs/Medsun/searchReportText.cfm>
21. </scripts/cdrh/cfdocs/cfClia/Search.cfm>
22. </scripts/cdrh/cfdocs/cfTPLC/tplc.cfm>
23. [./detail.cfm?standard__identification_no=41539](/detail.cfm?standard__identification_no=41539)
24. [./detail.cfm?standard__identification_no=41535](/detail.cfm?standard__identification_no=41535)
25. [./detail.cfm?standard__identification_no=41537](/detail.cfm?standard__identification_no=41537)
26. [./detail.cfm?standard__identification_no=43309](/detail.cfm?standard__identification_no=43309)
27. [./detail.cfm?standard__identification_no=44029](/detail.cfm?standard__identification_no=44029)
28. [./detail.cfm?standard__identification_no=41529](/detail.cfm?standard__identification_no=41529)
29. [./detail.cfm?standard__identification_no=41531](/detail.cfm?standard__identification_no=41531)

Page Last Updated: 07/28/2025

Note: If you need help accessing information in different file formats, see [Instructions for Downloading Viewers and Players](#).

Language Assistance Available: [Español](#) | [繁體中文](#) | [Tiếng Việt](#) | [한국어](#) | [Tagalog](#) | [Русский](#) | [العربية](#) | [Kreyòl Ayisyen](#) | [Français](#) | [Polski](#) | [Português](#) | [Italiano](#) | [Deutsch](#) | [日本語](#) | [فارسی](#) | [English](#)

[Accessibility](#) [Contact FDA](#) [Careers](#) [FDA Basics](#) [FOIA](#) [No FEAR Act](#) [Nondiscrimination](#) [Website Policies](#) / [Privacy](#)



U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)

[Contact FDA](#)



[For Government For Press](#)

[Combination Products](#) [Advisory Committees](#) [Science & Research](#) [Regulatory Information](#) [Safety](#) [Emergency](#) [Preparedness](#) [International Programs](#) [News & Events](#) [Training and Continuing Education](#) [Inspections/Compliance](#) [State & Local Officials](#) [Consumers](#) [Industry Health Professionals](#) [FDA Archive](#) [Vulnerability Disclosure Policy](#)



U.S. Department of **Health & Human Services**

Links on this page:

1. <http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain>
2. <http://www.addthis.com/bookmark.php>
3. <https://www.fda.gov/>
4. <https://www.fda.gov/Medical-Devices>
5. <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases>
6. <https://www.fda.gov/medical-devices/standards-and-conformity-assessment-program/asca-accredited-testing-laboratories>
7. </scripts/cdrh/devicesatfda/index.cfm>
8. </scripts/cdrh/cfdocs/cfPMN/pmn.cfm>

9. /scripts/cdrh/cfdocs/cfpmn/denovo.cfm
10. /scripts/cdrh/cfdocs/cfRL/rl.cfm
11. /scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfm
12. /scripts/cdrh/cfdocs/cfRES/res.cfm
13. /scripts/cdrh/cfdocs/cfPMA/pma.cfm
14. /scripts/cdrh/cfdocs/cfHDE/hde.cfm
15. /scripts/cdrh/cfdocs/cfPCD/classification.cfm
16. /scripts/cdrh/cfdocs/cfStandards/search.cfm
17. /scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm
18. /scripts/cdrh/cfdocs/cfPCD_RH/classification.cfm
19. /scripts/cdrh/cfdocs/cfAssem/assembler.cfm
20. /scripts/cdrh/cfdocs/Medsun/searchReportText.cfm
21. /scripts/cdrh/cfdocs/cfClia/Search.cfm
22. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm
23. ./detail.cfm?standard__identification_no=41539
24. ./detail.cfm?standard__identification_no=41535
25. ./detail.cfm?standard__identification_no=41537
26. ./detail.cfm?standard__identification_no=43309
27. ./detail.cfm?standard__identification_no=44029
28. ./detail.cfm?standard__identification_no=41529
29. ./detail.cfm?standard__identification_no=41531