



SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

F2 LABS
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ELECTRICAL

Valid To: November 30, 2025

Certificate Number: 0793.02

In recognition of the successful completion of the A2LA evaluation process (including an assessment of the organization's compliance with A2LA's FDA ASCA Accreditation Program¹ requirements), accreditation is granted to this laboratory to perform the following electrical tests:

Tests (Parameters):

Emissions (up to 40 GHz)
Generic or Product Specific

Standard(s):

EN 50270; BS 50270; EN 55015; EN 60601-1-2;
BS 60601-1-2; EN 61000-6-3; BS 61000-6-3;
EN 61000-6-4; BS 61000-6-4; EN 61326-1; BS 61326-1;
EN 61326-2-1; BS 61326-2-1; EN 50370-1; BS 50370-1;
EN 61326-2-2; BS 61326-2-2; EN 61326-2-3; BS 61326-2-3;
EN 61326-2-4; BS 61326-2-4; EN 61326-2-5; BS 61326-2-5;
EN 61326-2-6; BS 61326-2-6; EN 61851-21-2;
BS 61851-21-2; EN 55014-1; BS 55014-1;
EN 62233; BS 62233; IEC 62233;
EN 14982; BS 14982; ISO 14982;
IEC 61326-1; IEC 61326-2-1; IEC 61326-2-2;
IEC 61326-2-3; IEC 61326-2-4; CISPR 12; ICES-002;
IEC 61326-2-5; IEC 61326-2-6; IEC 61851-21-1;
CAN/CSA CISPR 12;
IEC 60601-1-2¹; IEC 60601-1-2 Ed. 3.0 b:2007¹;
EN 60601-1-2:2007/AC:2010; BS 60601-1-2 2007+ C 2010;
EN 60601-1-2:2015; BS 60601-1-2 2015;
IEC 60601-1-2 Ed. 4.0:2014¹; KS C IEC 60601-1-2;
IEC 61000-6-3; KS C 9610-6-3;
KS C 9610-6-4; IEC 61000-6-4;
IEC 55014-1; CISPR 14-1; AS/NZS CISPR 14.1;
CISPR 15;
KS C 9814-1; KS C 9815;
CNS 13438 (up to 6 GHz);
KS C 9832; CISPR 32; EN 55032; BS 55032;
SI 961 Part 32; IMDA TS SRD;
IEC 60533; IEC 60092-504; IEC 60945;
CISPR 16-1-4; CISPR 16-2-1; CISPR 16-2-3;
IEC 60601-2-64 (Section 201.17)¹;
IEC 60601-2-1 (Section 201.17)¹;
ANSI C63.27:2017

Tests (Parameters):**Standard(s):***Basic Standards*

(Conducted;

Radiated – 9 kHz to 40 GHz;
3m / 10m site)CFR 47, FCC Part 15, Part B (using ANSI C63.4:2014);
CFR 47, FCC Part 18 (using MP-5:1986);
CFR 47, FCC Part 15, Part C (using ANSI C63.10:2013);
ANSI C63.4:2009, 2014; ICES-001; ICES-003;
ANSI C63.10:2013; VCCI-CISPR 32:2016 (*up to 6 GHz*);
CNS 13438 (*up to 6 GHz*); AS/NZS 3548; IEC 60533;
IEC 60092-504; CISPR 16-1-4; CISPR 16-2-1; CISPR 16-2-3;
EN 55011; BS 55011; KS C 9811; CISPR 11;
KN 22; CISPR 22; EN 55022; BS 55022; SI 961 Part 32

Current Harmonics

IEC/EN 61000-3-2; BS 61000-3-2; KS C 9610-3-2

Voltage Fluctuations and Flicker

IEC/EN 61000-3-3; BS 61000-3-3; KS C 9610-3-3

Immunity*Generic or Product Specific*IEC 60601-1-2 ¹; EN 60601-1-2:2015; BS 60601-1-2 2015;
EN 60601-1-2:2007/AC:2010; BS 60601-1-2:2007/AC:2010;
EN 14982; BS 14982; ISO 14982;
IEC 60601-1-2 Ed. 3.0 b:2007 ¹; IEC 60601-1-2 Ed. 4.0:2014 ¹;
AIM 7351731; SI 961 Part 24;
EN 61547; BS 61547; EN 61000-6-1; BS 61000-6-1;
EN 61000-6-2; BS 61000-6-2; EN 55024; BS 55024;
EN 61326-1; BS 61326-1; EN 60601-1-2; BS 60601-1-2;
EN 50270; BS 50270; EN 301 489-1;
EN 61851-21-2; BS 61851-21-2;
EN 301 489-3; EN 301 489-17; EN 301 489-52;
IEC 61000-6-1; IEC 61000-6-2; EN 50370-2; BS 50370-2;
IEC 55024; IEC 61326-1; IEC 61851-21-2; IMDA TS SRD;
ANSI/RESNA WC-2 2009, Section 21;
ISO 7176-21:2009; KS C 9835;
UL 2331-2; UL 2202 (using UL 991 per clause 36.2);
IEC 61547; IEC 60533; IEC 60092-504; IEC 60945;
KS C IEC 60601-1-2; KN 24; KS C 9814-2; KS C 9547;
KS C 9610-6-1; KS C 9610-6-2; KS X 3124;
KS X 3125; KS X 3126;
CISPR 14-2; AS/NZS CISPR 14.2;
CISPR 24; IEC 55014-2; EN 55014-2; BS 55014-2; ISO 22200

Basic Standards

EN 61000-4-2; BS 61000-4-2; IEC 61000-4-2

Electrostatic Discharge (ESD)

KS C 9610-4-2

Radiated Immunity

EN 61000-4-3; BS 61000-4-3; IEC 61000-4-3; KS C 9610-4-3

Electrical Fast Transient/Burst

EN 61000-4-4; BS 61000-4-4; IEC 61000-4-4; KS C 9610-4-4

Surge Immunity

EN 61000-4-5; BS 61000-4-5; IEC 61000-4-5; KS C 9610-4-5

Conducted Immunity

EN 61000-4-6; BS 61000-4-6; IEC 61000-4-6; KS C 9610-4-6

Tests (Parameters):**Standard(s):**

Power Frequency Magnetic
Field Immunity

EN 61000-4-8; BS 61000-4-8; IEC 61000-4-8; KS C 9610-4-8

Voltage Dips, Short Interruptions,
and Line Voltage Variations

EN 61000-4-11; BS 61000-4-11;
IEC 61000-4-11; KS C 9610-4-11;
IEC 61000-4-16; EN 61000-4-16; BS 61000-4-16

Radio (up to 40 GHz)
(excluding SAR and DFS)

CFR 47, FCC Part 15, Subpart C (using ANSI C63.10:2013);
CFR 47, FCC Part 15, Subpart E (*without DFS*),
(using ANSI C63.10:2013);
RSS-GEN, Issue 5 (April 2018, Amendment 1 – March 2019,
Amendment 2 – February 2021);
RSS-102 measurement (RF Exposure), Issue 5, (March 2015,
Amendment 1 – February 2021);
RSS-210, Issue 10 (December 2019, Amendment April 2020);
RSS-247 (*without DFS*), Issue 3 (August 2023);
EN 300 220-2; EN 300 328; EN 300 330-2;
EN 300 440-1; EN 300 440-2;
IMDA TS SRD

RF Exposure

IEEE C95.1; IEEE C95.3;
ICNIRP Guidelines Vol. 74 #4;
RSS-102 measurement (RF Exposure - MPE only), Issue 5,
(March 2015)

Avionics/Military

DO 160-Sections 21 and 25;
NFPA 1982- Sections 8.19-8.21 for PASS devices

Medical

IEC 60601-2-1 Edition 4.0 2020-10 (Section(s) 201.17/202)¹

IEC 60601-2-10 Edition 2.1 2016-04 (Section(s) 201.17/202)¹;

IEC 60601-2-11 Edition 3.0 2013-01 (Section(s) 201.17/202)¹;

ANSI AAMI IEC 60601-2-16:2018 (Section(s) 201.17/202)¹;
IEC 60601-2-18: Edition 3.0 2009-08 (Section(s) 201.17/202)¹;
ANSI AAMI IEC 60601-2-19 Edition 2.1 2016-04;
ANSI AAMI IEC 60601-2-19 Edition 3.0 2020-09;

ANSI AAMI IEC 60601-2-2:2017 (Section(s) 201.17/202)¹;
ANSI AAMI IEC 60601-2-20 Edition 2.1 2016-04
(Section(s) 201.17/202)¹;
ANSI AAMI IEC 60601-2-20 Edition 3.0 2020-09
(Section(s) 201.17/202)¹;

ANSI AAMI IEC 60601-2-21 Edition 2.1 2016-04;
ANSI AAMI IEC 60601-2-21 Edition 3.0 2020-09

IEC 60601-2-22 Edition 3.1 2012-10 (Section(s) 201.17/202)¹;
IEC 60601-2-23 Edition 3.0 2011-02 (Section(s) 201.17/202)¹;

Tests (Parameters):

Medical
(cont.)

Standard(s):

IEC 60601-2-25 Edition 2.0 2011-10¹;
ANSI AAMI IEC 60601-2-25:2011/(R)2016¹
ANSI AAMI IEC 60601-2-25 Edition 2.0 2011-10
(Section(s) 201.17/202);
ANSI AAMI IEC 60601-2-27:2011(R)2016¹;
IEC 60601-2-28 Edition 2.0 2010-03 (Section(s) 201.17/202)¹;
IEC 60601-2-28 Edition 3.0 2017-06 (Section(s) 201.17/202)¹;
IEC 60601-2-29 Edition 3.0 2008-06 (Section(s) 201.17/202)¹;
IEC 60601-2-31 Edition 2.1 2011-09 (Section(s) 201.17/202)¹;
IEC 60601-2-33 Edition 4.0 2022-08 (Section(s) 201.17/202)¹;
IEC 60601-2-34 Edition 3.0 2011-05 (Section(s) 201.17/202)¹;
IEC 60601-2-36 Edition 2.0 2014-04 (Section(s) 201.17/202)¹;

IEC 60601-2-37 Edition 2.1 2015 (Section(s) 201.17/202)¹;
IEC 60601-2-43 - Ed. 2.0 2010-03 (Section(s) 201.17/202)¹;
IEC 60601-2-43 Edition 2.1 2017-05
CONSOLIDATED VERSION (Section(s) 201.17/202)¹;
IEC 60601-2-43 Edition 3.0 2022-12(Section(s) 201.17/202);
IEC 60601-2-44 Edition 3.2: 2016 (Section(s) 201.17/202)¹;
IEC 60601-2-45 Edition 3.1 2015 (Section(s) 201.17/202)¹;
ANSI AAMI IEC 60601-2-47:2012/(R)2016¹;
IEC 60601-2-5: Edition 3.0 2009-07 (Section(s) 201.17/202)¹;
ANSI AAMI IEC 60601-2-50 Edition 2.1 2016-04
(Section(s) 201.17/202)¹;
IEC 60601-2-50 Edition 3.0 2020-09 (Section(s) 201.17/202)¹;
IEC 60601-2-52 Edition 1.1 2015-03 CONSOLIDATED
VERSION (Section(s) 201.17/202)¹;
IEC 60601-2-54 Edition 2.0 2022-09;
IEC 60601-2-57 Edition 1.0 2011-01 (Section(s) 201.17/202)¹;
IEC 60601-2-6 Edition 2.1 2016-04 (Section(s) 201.17/202)¹;
IEC 60601-2-64 Edition 1.0 2014-09 (Section(s) 201.17/202)¹;
IEC 60601-2-8 Edition 2.1 b:2015 (Section(s) 201.17/202)¹;
ISO 80601-2-12 First Edition 2011-04-15
(Section(s) 201.17/202)¹;
ISO 80601-2-12 Second Edition 2020-02
(Section(s) 201.17/202)¹;
ISO 80601-2-55 Second Edition 2018-02
(Section(s) 201.17/202)¹;
ISO 80601-2-56 Second Edition 2017-03
(Section(s) 201.17/202)¹;
IEC 80601-2-59 Edition 2.0 2017-09 (Section(s) 201.17/202)¹;
IEC 80601-2-60 Edition 2.0 2019-06 (Section(s) 201.17/202)¹;
ISO 80601-2-61 Second Edition 2017-12¹;
(Corrected version 2018-02) (Section(s) 201.17/202)¹;
ISO 80601-2-69 Second Edition 2020-11
(Section(s) 201.17/202)¹;
(Section(s) 201.17/202)¹;
ISO 80601-2-70 Second edition 2020-11
(Section(s) 201.17/202)¹;
ISO 80601-2-80 First Edition 2018-07 (Section(s) 201.17/202)¹;

Tests (Parameters):**Standard(s):****Field Testing – In situ Methods ²:*****Emissions****Generic or Product Specific*

IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED
VERSION ¹

CFR 47, FCC Part 15, Subpart B (using ANSI C63.4:2014);
CFR 47, FCC Part 18 (using MP-5:1986);
ANSI C63.4:2009;
EN 60601-1-2:2015; BS 60601-1-2 2015;
EN 60601-1-2:2007/AC:2010; BS 60601-1-2 2007+ C 2010;

IEC 60601-1-2 Ed. 4.0:2014 ¹;
IEC 60601-1-2 Ed. 3.0 b:2007 ¹; EN 60601-1-2; BS 60601-1-2;
EN 61000-6-3; BS 61000-6-3; EN 61000-6-4;
EN 61326-1; BS 61326-1;
EN 55014-1; BS 55014-1; IEC 55014-1;
IEC 60601-1-2 ¹; IEC 61000-6-3; IEC 61000-6-4;
IEC 61326-1; CISPR 14-1; EN 50370-1;
EN 55011; EN 55022; BS 55022;
ICES-001; ICES-003, Issue 6; ICES-002;
CISPR 11; CISPR 12; CISPR 22; CAN/CSA CISPR 12;
EN 14982; ISO 14982

Immunity*Generic or Product Specific*

EN 60601-1-2:2015; BS 60601-1-2 2015;
EN 60601-1-2:2007/AC:2010; BS 60601-1-2 2007+ C 2010;
IEC 60601-1-2 Ed. 4.0:2014 ¹;
IEC 60601-1-2 Ed. 3.0 b:2007 ¹;
EN 61000-6-1; EN 61000-6-2; BS 61000-6-2; EN 55024;
EN 14982; ISO 14982; EN 61326-1; BS 61326-1;
EN 60601-1-2; BS 60601-1-2; IEC 61000-6-1;
IEC 61000-6-2; IEC 55024; IEC 61326-1; EN 50370-2;
IEC 60601-1-2 ¹;
CISPR 14-2; CISPR 24; ISO 22200;
EN 61000-4-2; BS 61000-4-2; IEC 61000-4-2;
EN 61000-4-3; BS 61000-4-3; IEC 61000-4-3;
EN 61000-4-4; BS 61000-4-4; IEC 61000-4-4;
EN 61000-4-5; BS 61000-4-5; IEC 61000-4-5;
EN 61000-4-6; BS 61000-4-6; IEC 61000-4-6;
EN 61000-4-8; BS 61000-4-8; IEC 61000-4-8;
EN 61000-4-11; BS 61000-4-11; IEC 61000-4-11

RF Exposure

IEEE C95.1; IEEE C95.3;
ICNIRP Guidelines Vol. 74 #4

***Radio Frequency Identification
(RFID)***

ISO 20912;
ISO 20909 (Section 5.5.2)

Tests (Parameters):**Standard(s):****Safety:**

Industrial, Machinery,
and Controls ²

UL: 22, 67, 98, 293, 294, 325, 353, 429, 508, 508a, 508b, 508c, 508e, 541, 561, 632, 751, 756, 763, 778, 863, 867, 873, 916, 917, 984, 1004-1 to -8, 1008, 1069, 1433, 1472, 1564, 1594, 1647, 2157, 2158, 60839-11-1;
NFPA 79;
CSA: 10, 14, 46, 100, 113, 128, 178, 195, 301, Z432, 60839-11-1;
IEC/EN: 4413, 4414, 12100, 13849-1, 13849-2, 60092-504, 60204-1, 60204-11, 60204-31, 60204-32, 60839-11-1;
BS: 12100, 13849-1, 13849-2, 60092-504, 60204-1, 60204-11, 60204-31

Laboratory ²

UL: 61010-1 (including all part 2s), 61010A-1 (including all part 2s), 61010B-1 (including all part 2s), 61010C-1, 1262, 3111-1;
CSA 61010-1 (including all part 2s);
EN 61010-1 (including all part 2s);
IEC 61010-1 (including all part 2s);
BS 61010-1 (including all part 2s);
IEC 61010-1 Edition 3.1 2017-01 CONSOLIDATED VERSION

Medical ²

UL: 544, 1069, 2601-1, 60601-1, 60601-1-4, 60601-1-6, 60601-1-8, 60601-1-11, 60601 (including all part 2s);
ANSI/AAMI ES60601-1; ANSI/AAMI HA60601-1-11;
CSA: 601.1, 60601-1, 60601-1-4, 60601-1-6, 60601-1-8, 60601-1-11, 60601 (including all part 2s);
IEC: 60601-1, 60601-1-4, 60601-1-6, 60601-1-8, 60601-1-11, 60601 (including all part 2s), 62366, 62304, 80601 (all part 2s);
EN: 60601-1, 60601-1-4, 60601-1-6, 60601-1-8, 60601-1-11, 60601 (including all part 2s), 62366, 62304, 80601 (all part 2s),
EN 45502-1 (including all part 2s);
ISO 7176-14/RESNA WC-2 Section 14; ISO 7176-25;
BS: 60601-1, 60601-1-6, 60601-1-8, 60601-1-11, 60601 (including all part 2s), 62366, 62304, 80601 (all part 2s)
ANSI AAMI 60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021];

Tests (Parameters):

Medical² (cont.)

Standard(s):

IEC 60601-1 Edition 3.2 2020-08 CONSOLIDATED
VERSION

ANSI AAMI HA60601-1-11:2015 [Including AMD1:2021];
IEC 60601-1-11 Edition 2.1 2020-07 CONSOLIDATED
VERSION;

IEC 60601-1-10 Edition 1.2 2020-07 CONSOLIDATED
VERSION;

IEC 60601-1-6 Edition 3.2 2020-07 CONSOLIDATED
VERSION;

ANSI AAMI IEC 60601-1-8:2006 and A1:2012 [Including
AMD 2:2021];
IEC 60601-1-8 Edition 2.1 2012-11;
IEC 60601-1-8 Edition 2.2 2020-07 CONSOLIDATED
VERSION;

ANSI AAMI IEC 60601-1-12:2016 [Including AMD 1:2021];
IEC 60601-1-12 Edition 1.0 2014-06;
IEC 60601-1-12 Edition 1.1 2020-07 CONSOLIDATED
VERSION;

IEC 60601-2-10 Edition 2.1 2016-04;

IEC 60601-2-18 Edition 3.0 2009-08;

ANSI AAMI IEC 60601-2-19 Edition 2.1 2016-04;
ANSI AAMI IEC 60601-2-19 Edition 3.0 2020-09;

ANSI AAMI IEC 60601-2-2:2017;
IEC 60601-2-2 Edition 6.0 2017-03;
IEC 60601-2-2 Edition 6.1 2023-02;

ANSI AAMI IEC 60601-2-20 Edition 2.1 2016-04;
ANSI AAMI IEC 60601-2-20 Edition 3.0 2020-09;

IEC 60601-2-21 Edition 2.1 2016-04;
IEC 60601-2-21 Edition 3.0 2020-09;

IEC 60601-2-22 Edition 3.1 2012-10;
ANSI AAMI IEC 60601-2-25:2011/(R)2016;
IEC 60601-2-25 Edition 2.0 2011-10;
ANSI AAMI IEC 60601-2-27:2011(R)2016;
IEC 60601-2-27 Edition 3.0 2011-03;

ANSI AAMI IEC 60601-2-47:2012/(R)2016;
IEC 60601-2-47 Edition 2.0 2012-02;

Tests (Parameters):**Standard(s):**Medical ² (*cont.*)IEC 60601-2-52 Edition 1.1 2015-03 CONSOLIDATED
VERSION(Section(s) 201.17/202) 1

IEC 60601-2-57 Edition 1.0 2011-01;

IEC 60601-2-6 Edition 2.1 2016-04;

IEC 80601-2-35 Edition 2.1 2016-04;

IEC 60601-2-35 Edition 2.0 2020-09;

IEC 80601-2-59 Edition 2.0 2017-09;

IEC 80601-2-60 Edition 2.0 2019-06;

ISO 80601-2-56 Second Edition 2017-03;

ISO 80601-2-69 Second Edition 2020-11;

ISO 80601-2-74 First Edition 2017-05;

Household Appliances ²UL: 73, 82, 130, 141, 174, 197, 244a, 250, 471, 484, 498, 499,
507,563, 621, 749, 826, 858, 859, 921, 923, 982, 998, 1005, 1017,
1018,1026, 1028, 1042, 1083, 1086, 1206, 1261, 1278, 1286, 1431,
1445,

1563, 1638, 1727, 1995, 60335-1 (including all part 2s),

60730-1 (including all part 2s);

CSA: 64-10, 68, 236, 243, 60335-1 (including all part 2s),

60730-1 (including all part 2s);

IEC/EN: 60335-1 (including all part 2s), 60730-1 (including all
part 2s);BS: 60335-1 (including all part 2s), 60730-1 (including all part
2s)IT Equipment,
Audio, Video, and Communication ²UL: 122, 469, 813, 1459, 1492, 2044, 3044, 60065-1, 60950-1,
62368-1;

CSA: 107.3, 60065-1, 60950-1, 62368-1;

IEC/EN/BS: 60065-1, 60950-1, 60950-22,

60945 (*excluding sections 10, 11, & 11.2*), 62040-1, 62368-1;

AS/NZS: 60065-1, 60950-1, 62040-1, 62368-1;

BS: 60950-1, 60950-22, 62368-1

Lighting ²UL: 48, 482, 153, 298, 496, 542, 676, 924, 935, 970, 1029,
1088, 1230,

1573, 1574, 1598, 1786, 1838, 1993, 2108, 2703, 8750,

60598-1 (including all part 2s);

CSA: 12, 89, 166, 207, 250 (including all parts), E60598-1;

IEC/EN: 60598-1, 61347-1 (including all part 2s);

BS: 60598-1, 61347-1 (including all part 2s)

Tests (Parameters):**Standard(s):**

Power Supplies
and Transformers ²
Tools ²

UL: 506, 697, 1012, 1236, 1310, 1561, 1562, 1585, 2161;
CSA: 47, 107.1, 107.2
UL: 45, 987, 1447, 1448, 60745-1 (including all part 2s),
62841-1 (including all particular standards);
CSA: 60745-1 (including all part 2s),
62841-1 (including all particular standards);
IEC/EN: 60745-1 (including all part 2s),
62841-1 (including all particular standards);
BS: 60745-1 (including all part 2s),
62841-1 (including all particular standards)

Enclosures ²

UL: 50, 50e, 514;
CSA: 0.4, 94-1, 94-2;
IEC/EN 60529, BS 60529;
NEMA 250, ISO 20653

Other ²

UL: 609, 696, 869a, 961, 962, 969, 1097, 1244, 1418, 2305,
2361;
EN 50085-1 (including all part 2s);
EN/IEC 63000, CSA 203, SPE1000, SPE3000

On the following types of products/equipment:

Information Technology Equipment (ITE), Scientific Equipment, Industrial Equipment, Test & Measurement Equipment, Lighting Equipment, Household Appliances / Electric Tools, Audio/Video Equipment, Medical Equipment, Electrical Control Equipment, and Electrical Laboratory Equipment.

Testing Activities performed under the scope of the U.S FDA ASCA Pilot Program Specifications: *Basic Safety and Essential Performance of Medical Electrical Equipment, Medical Electrical Systems, and Laboratory Medical Equipment – Standards Specific Information for the Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program* published on September 25th, 2020, and in accordance with all requirements of A2LA R256 *Specific Requirements- FDA ASCA Program* ³:

<u>Standards:</u>	<u>Document Number:</u>
IEC 60601-2-1 Edition 4.0 2020-10 (Section(s) 201.17/202)	12-338
IEC 60601-2-10 Edition 2.1 2016-04 (Section(s) 201.17/202)	17-16
IEC 60601-2-11 Edition 3.0 2013-01 (Section(s) 201.17/202)	12-255
ANSI AAMI IEC 60601-2-16:2018 (Section(s) 201.17/202)	9-121

Testing Activities performed under the scope of the U.S FDA ASCA Pilot Program Specifications: *Basic Safety and Essential Performance of Medical Electrical Equipment, Medical Electrical Systems, and Laboratory Medical Equipment – Standards Specific Information for the Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program* published on September 25th, 2020, and in accordance with all requirements of A2LA R256 *Specific Requirements- FDA ASCA Program*³:

<u>Standards:</u>	<u>Document Number:</u>
IEC 60601-2-18: Edition 3.0 2009-08 (Section(s) 201.17/202)	9-114
ANSI AAMI IEC 60601-2-19 Edition 3.0 2020-09	6-461
IEC 60601-2-22 Edition 3.1 2012-10 (Section(s) 201.17/202)	12-268
IEC 60601-2-23 Edition 3.0 2011-02 (Section(s) 201.17/202)	1-87
IEC 60601-2-25 Edition 2.0 2011-10	3-105
ANSI AAMI IEC 60601-2-25:2011/(R)2016	3-105
ANSI AAMI IEC 60601-2-27:2011(R)2016	3-126
IEC 60601-2-28 Edition 3.0 2017-06 (Section(s) 201.17/202)	12-309
IEC 60601-2-29 Edition 3.0 2008-06 (Section(s) 201.17/202)	12-211
IEC 60601-2-31 Edition 2.1 2011-09 (Section(s) 201.17/202)	3-102
IEC 60601-2-33 Edition 4.0 2022-08 (Section(s) 201.17/202)	12-347
IEC 60601-2-34 Edition 3.0 2011-05 (Section(s) 201.17/202)	3-115
IEC 60601-2-36 Edition 2.0 2014-04 (Section(s) 201.17/202)	9-119
IEC 60601-2-37 Edition 2.1 2015 (Section(s) 201.17/202)	12-293
IEC 60601-2-43 Edition 3.0 2022-12(Section(s) 201.17/202)	12-351
IEC 60601-2-44 Edition 3.2: 2016 (Section(s) 201.17/202)	12-302
IEC 60601-2-45 Edition 3.1 2015 (Section(s) 201.17/202)	12-294
ANSI AAMI IEC 60601-2-47:2012/(R)2016	3-155
IEC 60601-2-5: Edition 3.0 2009-07 (Section(s) 201.17/202)	12-205
IEC 60601-2-50 Edition 3.0 2020-09 (Section(s) 201.17/202)	6-450
IEC 60601-2-52 Edition 1.1 2015-03 CONSOLIDATED VERSION (Section(s) 201.17/202)	6-489
IEC 60601-2-57 Edition 1.0 2011-01 (Section(s) 201.17/202)	12-242
IEC 60601-2-6 Edition 2.1 2016-04 (Section(s) 201.17/202)	6-423
IEC 60601-2-64 Edition 1.0 2014-09 (Section(s) 201.17/202)	12-318

Testing Activities performed under the scope of the U.S FDA ASCA Pilot Program Specifications: *Basic Safety and Essential Performance of Medical Electrical Equipment, Medical Electrical Systems, and Laboratory Medical Equipment – Standards Specific Information for the Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program* published on September 25th, 2020, and in accordance with all requirements of A2LA R256 *Specific Requirements- FDA ASCA Program*³:

<u>Standards:</u>	<u>Document Number:</u>
IEC 60601-2-8 Edition 2.1 b:2015 (Section(s) 201.17/202)	12-301
ANSI AAMI IEC 60601-1-2:2014 [Including AMD 1:2021]	19-36
IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION	19-36
ANSI AAMI ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021]	19-46
IEC 60601-1 Edition 3.2 2020-08 CONSOLIDATED VERSION	19-49
ANSI AAMI HA60601-1-11:2015 [Including AMD1:2021]	19-47
IEC 60601-1-11 Edition 2.1 2020-07 CONSOLIDATED VERSION	19-38
IEC 60601-1-10 Edition 1.2 2020-07 CONSOLIDATED VERSION	19-37
IEC 60601-1-6 Edition 3.2 2020-07 CONSOLIDATED VERSION	5-132
ANSI AAMI IEC 60601-1-8:2006 and A1:2012 [Including AMD 2:2021]	5-131
IEC 60601-1-8 Edition 2.2 2020-07 CONSOLIDATED VERSION	5-131
ANSI AAMI IEC 60601-1-12:2016 [Including AMD 1:2021]	19-39
IEC 60601-1-12 Edition 1.1 2020-07 CONSOLIDATED VERSION	19-39
IEC 60601-2-10 Edition 2.1 2016-04	17-16
IEC 60601-2-18 Edition 3.0 2009-08	9-114
ANSI AAMI IEC 60601-2-2:2017	6-389
IEC 60601-2-2 Edition 6.0 2017-03	6-389
IEC 60601-2-21 Edition 3.0 2020-09	6-463
IEC 60601-2-22 Edition 3.1 2012-10	12-268
ANSI AAMI IEC 60601-2-25:2011/(R)2016	3-105
IEC 60601-2-25 Edition 2.0 2011-10	3-105
ANSI AAMI IEC 60601-2-27:2011(R)2016	3-126
IEC 60601-2-27 Edition 3.0 2011-03	3-126
ANSI AAMI IEC 60601-2-47:2012/(R)2016	3-155
IEC 60601-2-47 Edition 2.0 2012-02	3-155
IEC 60601-2-52 Edition 1.1 2015-03 CONSOLIDATED VERSION	6-489
IEC 60601-2-57 Edition 1.0 2011-01	12-242
IEC 60601-2-6 Edition 2.1 2016-04	6-423

Testing Activities performed under the scope of the U.S FDA ASCA Pilot Program Specifications: <i>Basic Safety and Essential Performance of Medical Electrical Equipment, Medical Electrical Systems, and Laboratory Medical Equipment – Standards Specific Information for the Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program</i> published on September 25th, 2020, and in accordance with all requirements of A2LA R256 <i>Specific Requirements- FDA ASCA Program</i> ³ :	
<u>Standards:</u>	<u>Document Number:</u>
ISO 80601-2-12 Second Edition 2020-02 (Section(s) 201.17/202)	1-146
IEC 60601-2-35 Edition 2.0 2020-09	6-483
IEC 60601-2-37 Edition 2.1 2015	12-293
IEC 60601-2-54 Edition 2.0 2022-09	12-348
ISO 80601-2-55 Second Edition 2018-02 (Section(s) 201.17/202)	1-140
ISO 80601-2-56 Second Edition 2017-03 (Section(s) 201.17/202)	6-421
IEC 80601-2-59 Edition 2.0 2017-09	6-405
IEC 80601-2-60 Edition 2.0 2019-06	4-262
ISO 80601-2-61 Second Edition 2017-12 (Corrected version 2018-02) (Section(s) 201.17/202)	1-139
ISO 80601-2-69 Second Edition 2020-11	1-148
ISO 80601-2-56 Second Edition 2017-03	6-421
ISO 80601-2-70 Second edition 2020-11	1-151
ISO 80601-2-74 First Edition 2017-05	1-138
ISO 80601-2-80 First Edition 2018-07 (Section(s) 201.17/202)	1-144
IEC 61010-1 Edition 3.1 2017-01 CONSOLIDATED VERSION	19-34

¹ The laboratory is only accredited for testing activities outlined within the test methods listed above. Reference to any other activity within these standards, such as risk management or risk assessment, does not fall within the laboratory's accredited capabilities

² This laboratory performs field testing activities for these tests.

³ These methods have been assessed by A2LA according to A2LA's FDA ASCA Program requirements. Accreditation by A2LA does not imply FDA ASCA-Accreditation. All ASCA-accreditation decisions for testing laboratory applications are made solely by the FDA, a list of approved laboratories can be found at FDA.gov.

Testing Activities Performed in Support of FCC Certification in Accordance with 47 Code of Federal Regulations and FCC KDB 974614, Appendix A, Table A.1 ⁴:

Rule Subpart/Technology	Test Method	Maximum Frequency
<u>Unintentional Radiators</u> Part 15B	ANSI C63.4:2014	40000 MHz

Testing Activities Performed in Support of FCC Certification in Accordance with 47 Code of Federal Regulations and FCC KDB 974614, Appendix A, Table A.1 ⁴:

Rule Subpart/Technology	Test Method	Maximum Frequency
<u>Industrial, Scientific, and Medical Equipment</u> Part 18	FCC MP-5 (February 1986)	40000 MHz
<u>Intentional Radiators</u> Part 15C	ANSI C63.10:2013	40000 MHz
<u>U-NII without DFS Intentional Radiators</u> Part 15E	ANSI C63.10:2013	40000 MHz

⁴Accreditation does not imply acceptance to the FCC equipment authorization program. Please see the FCC website (<https://apps.fcc.gov/oetcf/eas/>) for a listing of FCC approved laboratories.



Accredited Laboratory

A2LA has accredited

F2 LABS

Middlefield, OH

for technical competence in the field of

Electrical 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 – FDA ASCA Program. 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 21st day of December 2023.

A blue ink signature of Mr. Trace McInturff, written in a cursive style.

Mr. Trace McInturff, Vice President, Accreditation Services
For the Accreditation Council
Certificate Number 793.02
Valid to November 30, 2025

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