

Department of Health and Human Services  
Food and Drug Administration  
**STANDARDS DATA REPORT FOR 510(k)s**  
(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

## TYPE OF 510(K) SUBMISSION

☒ Traditional☐ Special☐ AbbreviatedSTANDARD TITLE <sup>1</sup>

IEC 60601-1-2:2007 Ed: 3 Med Electrical Equipment Part 1-2: Gen Reqs for Basic Safety and Essential Perf. Collateral EMC

**Please answer the following questions**

Yes

No

Is this standard recognized by FDA <sup>2</sup>? ..... ☒ ☐FDA Recognition number <sup>3</sup> ..... #19-1Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? ..... ☒ ☐Is a summary report <sup>4</sup> describing the extent of conformance of the standard used included in the 510(k)? ..... ☒ ☐  
If no, complete a summary report table.Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? ..... ☒ ☐Does this standard include acceptance criteria? ..... ☒ ☐  
If no, include the results of testing in the 510(k).Does this standard include more than one option or selection of tests? ..... ☒ ☐  
If yes, report options selected in the summary report table.Were there any deviations or adaptations made in the use of the standard? ..... ☐ ☒  
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) <sup>5</sup>? ..... ☐ ☐Were deviations or adaptations made beyond what is specified in the FDA SIS? ..... ☐ ☒  
If yes, report these deviations or adaptations in the summary report table.Were there any exclusions from the standard? ..... ☐ ☒  
If yes, report these exclusions in the summary report table.Is there an FDA guidance <sup>6</sup> that is associated with this standard? ..... ☐ ☒  
If yes, was the guidance document followed in preparation of this 510k? ..... ☐ ☐

Title of guidance: .....

<sup>1</sup> The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]<sup>2</sup> Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm><sup>3</sup> <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm><sup>4</sup> The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and

address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

<sup>5</sup> The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm><sup>6</sup> The online search for CDRH Guidance Documents can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>



**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

**STANDARD TITLE**

IEC 60601-1-2:2007 Ed: 3 Med Electrical Equipment Part 1-2: Gen Reqs for Basic Safety and Essential Perf. Collateral EMC

**CONFORMANCE WITH STANDARD SECTIONS\***

<b>SECTION NUMBER</b> CISPR 11:2010	<b>SECTION TITLE</b> Radiated Emissions	<b>CONFORMANCE?</b> <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED ♦

**DESCRIPTION**

Industrial, scientific and medical equipment – Radio-frequency disturbance characteristics – Limits and methods of measurement

**JUSTIFICATION**

<b>SECTION NUMBER</b> IEC 61000-4-2:2008	<b>SECTION TITLE</b> Electrostatic Discharge Immunity	<b>CONFORMANCE?</b> <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED ♦

**DESCRIPTION**

Electromagnetic compatibility (EMC) - Part 4-2: Testing and measurement techniques Electrostatic discharge immunity test

**JUSTIFICATION**

<b>SECTION NUMBER</b> IEC 61000-4-3:2010	<b>SECTION TITLE</b> Radiated Electromagnetic Field Immunity	<b>CONFORMANCE?</b> <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED ♦

**DESCRIPTION**

Electromagnetic compatibility (EMC) -- Part 4-3: Testing and measurement techniques - Radiated, radio-frequency, electromagnetic field immunity test

**JUSTIFICATION**

\* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

♦ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

The burden time for this collection of information is estimated to average 1 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services  
Food and Drug Administration  
Office of Chief Information Officer  
Paperwork Reduction Act (PRA) Staff  
[PRASaff@fda.hhs.gov](mailto:PRASaff@fda.hhs.gov)

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."*

# **EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE**

STANDARD TITLE

IEC 60601-1-2:2007 Ed: 3 Med Electrical Equipment Part 1-2: Gen Reqs for Basic Safety and Essential Perf. Collateral EMC

## **CONFORMANCE WITH STANDARD SECTIONS\***

SECTION NUMBER IEC 61000-4-8:2009	SECTION TITLE Magnetic Field Immunity	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

Electromagnetic compatibility (EMC) -- Part 4-8: Testing and measurement techniques -Power frequency magnetic field immunity tests

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

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