How to Use Consensus Standards in Premarket Submissions

Scott Colburn, CAPT, USPHS
Director
CDRH Standards and Conformity Assessment Program
Office of Strategic Partnerships and Technology Innovation
Center for Devices and Radiological Health
U.S. Food and Drug Administration

Value of Consensus Standards

FDA

Enhance regulatory science

Promote quality

Improve patient access

Science-based least burdensome regulatory approach

Learning Objectives

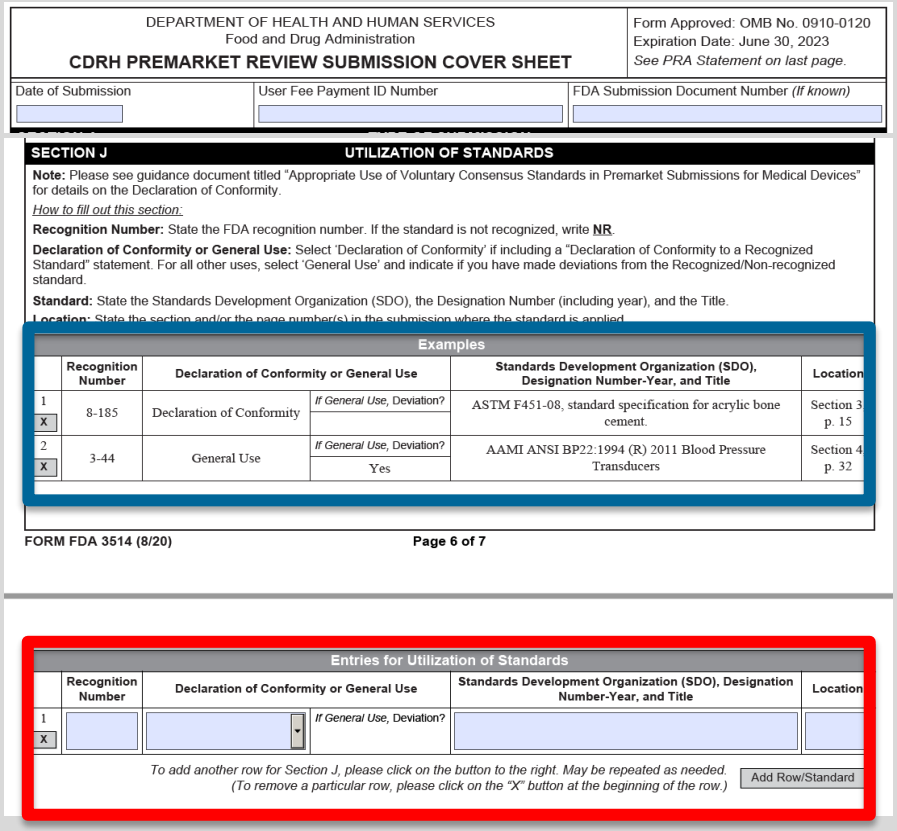
- Explain how to use standards in device submissions
- Describe how declarations of conformity (DOC) improve device review
- Identify when you need supplemental documentation
- Discuss *Helpful Tips* for using standards and DOCs in submissions

How to Use Consensus Standards in Device Submissions

Use of Consensus Standards

- Voluntary
- Only mandatory if cited in regulation
  - Example: 21 CFR 801 cites ASTM D3492
- In any type of submission
- With a DOC (recognized standards only), “General Use” (any standards, recognized or not) or both

How to Cite Standards-Cover Sheet



DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approved: OMB No. 0910-0120
Expiration Date: June 30, 2023
See PRA Statement on last page.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(If known)*

SECTION J **UTILIZATION OF STANDARDS**

Note: Please see guidance document titled "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices" for details on the Declaration of Conformity.

How to fill out this section:

Recognition Number: State the FDA recognition number. If the standard is not recognized, write **NR**.

Declaration of Conformity or General Use: Select 'Declaration of Conformity' if including a "Declaration of Conformity to a Recognized Standard" statement. For all other uses, select 'General Use' and indicate if you have made deviations from the Recognized/Non-recognized standard.

Standard: State the Standards Development Organization (SDO), the Designation Number (including year), and the Title.

Location: State the section and/or the page number(s) in the submission where the standard is applied.

Examples

	Recognition Number	Declaration of Conformity or General Use		Standards Development Organization (SDO), Designation Number-Year, and Title	Location
1 X	8-185	Declaration of Conformity	*If General Use,* Deviation?	ASTM F451-08, standard specification for acrylic bone cement.	Section 3 p. 15
2 X	3-44	General Use	*If General Use,* Deviation? Yes	AAMI ANSI BP22:1994 (R) 2011 Blood Pressure Transducers	Section 4 p. 32

FORM FDA 3514 (8/20) Page 6 of 7

Entries for Utilization of Standards

	Recognition Number	Declaration of Conformity or General Use		Standards Development Organization (SDO), Designation Number-Year, and Title	Location
1 X			*If General Use,* Deviation?		

To add another row for Section J, please click on the button to the right. May be repeated as needed.
(To remove a particular row, please click on the "X" button at the beginning of the row.)

Add Row/Standard

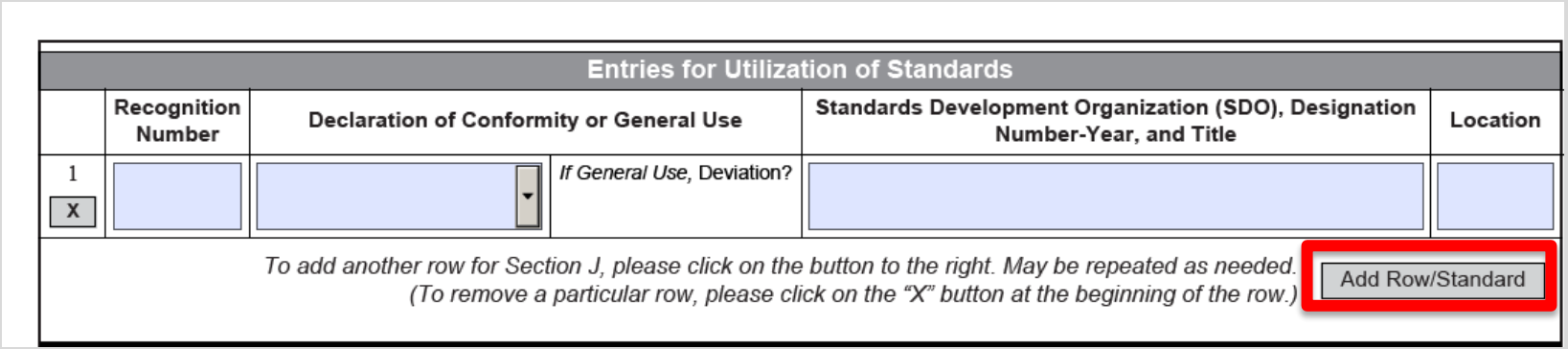
Form FDA 3514 Cover Sheet* Section J

- Examples Section
- Entries for Utilization of Standards

*** Download Form FDA 3514 "CDRH Premarket Review Submission Cover Sheet" at:**
www.fda.gov/media/72421/download

How to Cite Standards-Cover Sheet

Entries for Utilization of Standards



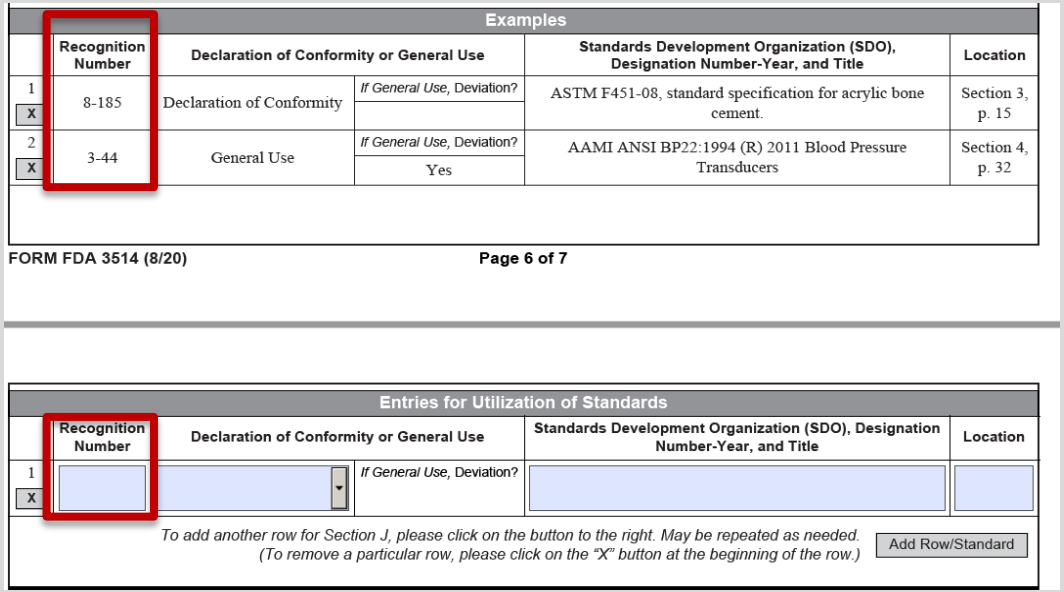
Entries for Utilization of Standards					
	Recognition Number	Declaration of Conformity or General Use		Standards Development Organization (SDO), Designation Number-Year, and Title	Location
1 X			*If General Use,* Deviation?		

To add another row for Section J, please click on the button to the right. May be repeated as needed.
(To remove a particular row, please click on the "X" button at the beginning of the row.)

Add Row/Standard

Add Row/Standard

How to Cite Standards-Cover Sheet



Examples

	Recognition Number	Declaration of Conformity or General Use		Standards Development Organization (SDO), Designation Number-Year, and Title	Location
1 X	8-185	Declaration of Conformity	*If General Use*, Deviation?	ASTM F451-08, standard specification for acrylic bone cement.	Section 3, p. 15
2 X	3-44	General Use	*If General Use*, Deviation? Yes	AAMI ANSI BP22:1994 (R) 2011 Blood Pressure Transducers	Section 4, p. 32

FORM FDA 3514 (8/20) Page 6 of 7

Entries for Utilization of Standards

	Recognition Number	Declaration of Conformity or General Use		Standards Development Organization (SDO), Designation Number-Year, and Title	Location
1 X			*If General Use*, Deviation?		

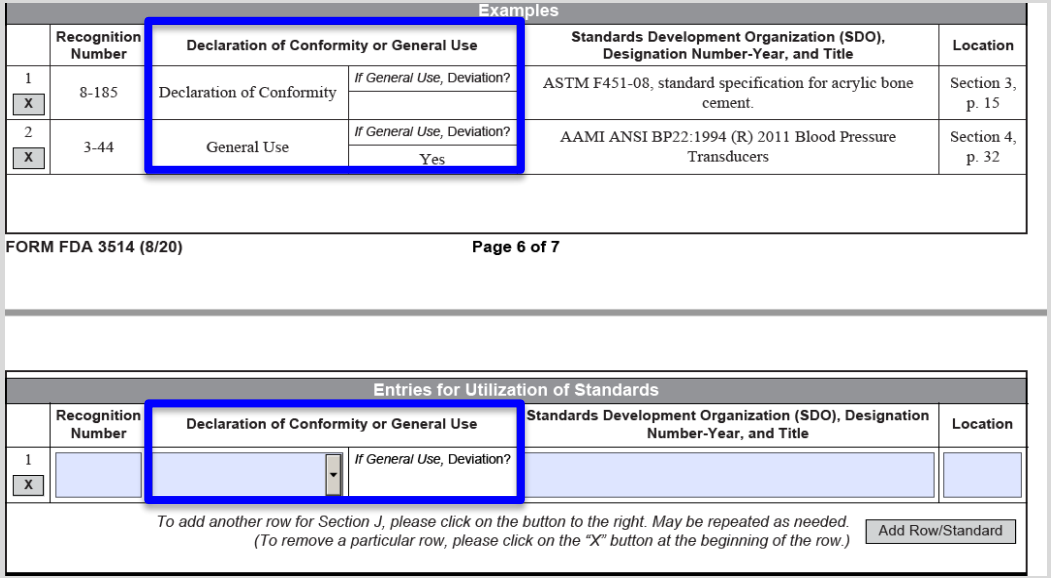
To add another row for Section J, please click on the button to the right. May be repeated as needed.
(To remove a particular row, please click on the "X" button at the beginning of the row.)

Add Row/Standard

Form 3514 Cover Sheet
Section J:
Recognition Number

Recognized Consensus Standards database
www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

How to Cite Standards-Cover Sheet



Examples

	Recognition Number	Declaration of Conformity or General Use		Standards Development Organization (SDO), Designation Number-Year, and Title	Location
1 X	8-185	Declaration of Conformity	*If General Use*, Deviation?	ASTM F451-08, standard specification for acrylic bone cement.	Section 3, p. 15
2 X	3-44	General Use	*If General Use*, Deviation? Yes	AAMI ANSI BP22:1994 (R) 2011 Blood Pressure Transducers	Section 4, p. 32

FORM FDA 3514 (8/20) Page 6 of 7

Entries for Utilization of Standards

	Recognition Number	Declaration of Conformity or General Use		Standards Development Organization (SDO), Designation Number-Year, and Title	Location
1 X			*If General Use*, Deviation?		

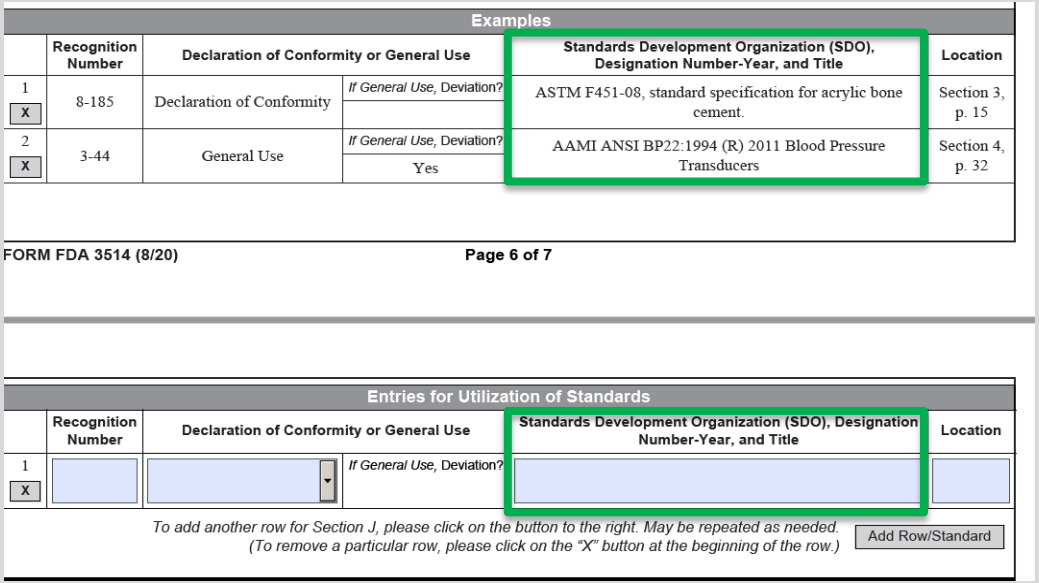
To add another row for Section J, please click on the button to the right. May be repeated as needed.
(To remove a particular row, please click on the "X" button at the beginning of the row.)

Add Row/Standard

Form 3514 Cover Sheet Section J:

Declaration of Conformity or General Use

How to Cite Standards-Cover Sheet



Examples

	Recognition Number	Declaration of Conformity or General Use		Standards Development Organization (SDO), Designation Number-Year, and Title	Location
1 X	8-185	Declaration of Conformity	*If General Use*, Deviation?	ASTM F451-08, standard specification for acrylic bone cement.	Section 3, p. 15
2 X	3-44	General Use	*If General Use*, Deviation? Yes	AAMI ANSI BP22:1994 (R) 2011 Blood Pressure Transducers	Section 4, p. 32

FORM FDA 3514 (8/20) Page 6 of 7

Entries for Utilization of Standards

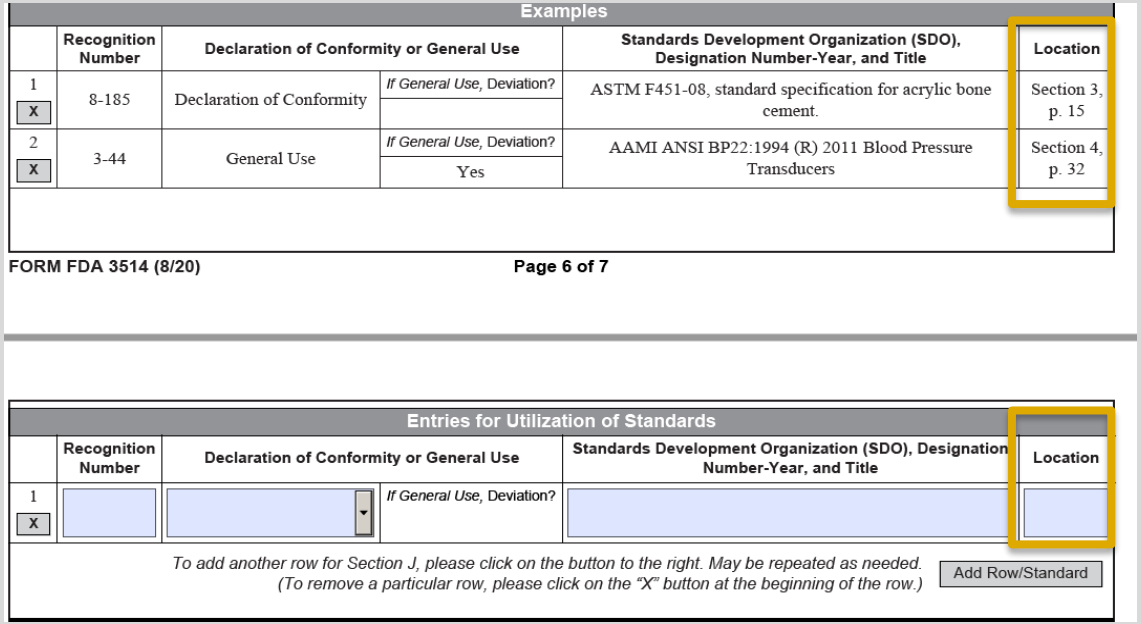
	Recognition Number	Declaration of Conformity or General Use		Standards Development Organization (SDO), Designation Number-Year, and Title	Location
1 X			*If General Use*, Deviation?		

To add another row for Section J, please click on the button to the right. May be repeated as needed.
(To remove a particular row, please click on the "X" button at the beginning of the row.)

Add Row/Standard

Form 3514 Cover Sheet
Section J:
Standard

How to Cite Standards-Cover Sheet



Examples

	Recognition Number	Declaration of Conformity or General Use		Standards Development Organization (SDO), Designation Number-Year, and Title	Location
1 X	8-185	Declaration of Conformity	*If General Use*, Deviation?	ASTM F451-08, standard specification for acrylic bone cement.	Section 3, p. 15
2 X	3-44	General Use	*If General Use*, Deviation? Yes	AAMI ANSI BP22:1994 (R) 2011 Blood Pressure Transducers	Section 4, p. 32

FORM FDA 3514 (8/20) Page 6 of 7

Entries for Utilization of Standards

	Recognition Number	Declaration of Conformity or General Use		Standards Development Organization (SDO), Designation Number-Year, and Title	Location
1 X			*If General Use*, Deviation?		

To add another row for Section J, please click on the button to the right. May be repeated as needed.
(To remove a particular row, please click on the "X" button at the beginning of the row.)

Add Row/Standard

Form 3514 Cover Sheet Section J:

Location (In Submission)

Declaration of Conformity (DOC)

What is a DOC?

- Attestation that device conforms with cited FDA-recognized standard
  - All normative requirements are met
  - All testing has been conducted
  - Testing is on finished device or final finished device
- If submitter declares conformity with a recognized standard, a DOC accompanies the submission

→ **Use of DOC with a recognized standard generally reduces documentation needed in a submission**

Elements of a DOC

- Name and address of applicant/sponsor responsible for DOC
- Product/device identification
- Statement of conformity
- List of standards to which DOC applies
- FDA recognition number for each standard

Please see ISO/IEC 17050-1:2004(en): *Conformity assessment-supplier's declaration of conformity-Part 1: General requirements* and FDA's guidance: *Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices*

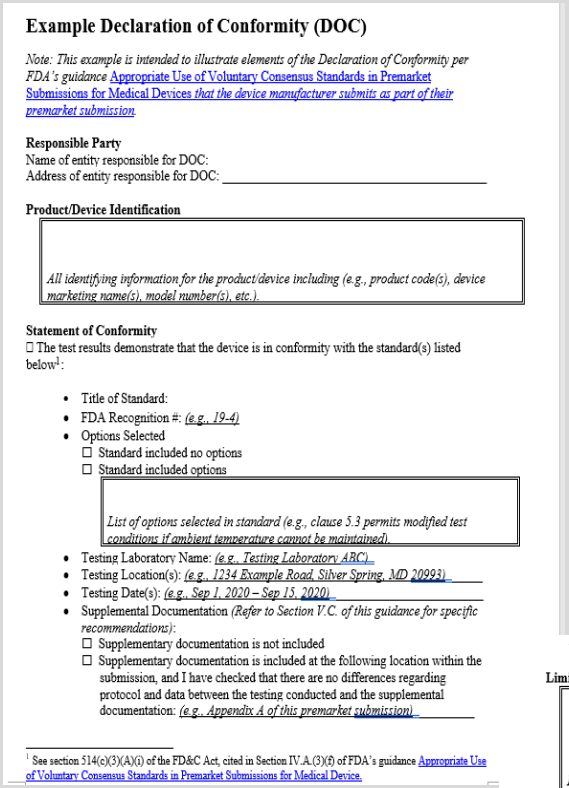
Elements of a DOC, cont'd

- Date and place of issuance of DOC
- Signature, printed name, and function of applicant/sponsor responsible for DOC
- Any limitation on validity of DOC (e.g., how long declaration is valid, what was tested, or concessions made about testing outcomes)
- Supplemental documentation per ISO 17050-2 or equivalent

Please see ISO/IEC 17050-1:2004(en): *Conformity assessment-supplier's declaration of conformity-Part 1: General requirements* and FDA's guidance: *Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices*

Elements of a DOC

- Responsible Party
- Product/Device Identification
- Statement of Conformity
- Limitations on Validity of DOC
- Signature



Example Declaration of Conformity (DOC)

Note: This example is intended to illustrate elements of the Declaration of Conformity per FDA's guidance Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices *that the device manufacturer submits as part of their premarket submission.*

Responsible Party
Name of entity responsible for DOC:
Address of entity responsible for DOC: _____

Product/Device Identification

All identifying information for the product/device including (e.g., product code(s), device marketing name(s), model number(s), etc.).

Statement of Conformity
☐ The test results demonstrate that the device is in conformity with the standard(s) listed below[1]:

- Title of Standard:
- FDA Recognition #: *(e.g., 19-4)*
- Options Selected
  - ☐ Standard included no options
  - ☐ Standard included options

  List of options selected in standard (e.g., clause 5.3 permits modified test conditions if ambient temperature cannot be maintained).
- Testing Laboratory Name: *(e.g., Testing Laboratory ABC)*
- Testing Location(s): *(e.g., 1234 Example Road, Silver Spring, MD 20993)*
- Testing Date(s): *(e.g., Sep 1, 2020 – Sep 15, 2020)*
- Supplemental Documentation *(Refer to Section V.C. of this guidance for specific recommendations)*:
  - ☐ Supplementary documentation is not included
  - ☐ Supplementary documentation is included at the following location within the submission, and I have checked that there are no differences regarding protocol and data between the testing conducted and the supplemental documentation: *(e.g., Appendix A of this premarket submission)*

[1] See section 514(c)(3)(A)(i) of the FD&C Act, cited in Section IV.A.(3)(f) of FDA's guidance Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Device.

<Repeat for each standard in DOC>

Limitations on Validity of DOC

Description of any limitation on the validity of the DOC (e.g., how long the declaration is valid, what was tested, or concessions made about the testing outcomes

Signature

Printed name: _____
Function within entity responsible for DOC:

_____
Signature Date

Responsible Party and Product/Device Identification

Example Declaration of Conformity (DOC)

Note: This example is intended to illustrate elements of the Declaration of Conformity per FDA's guidance Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices *that the device manufacturer submits as part of their premarket submission.*

Responsible Party
Name of entity responsible for DOC:
Address of entity responsible for DOC: _____

Product/Device Identification

All identifying information for the product/device including (e.g., product code(s), device marketing name(s), model number(s), etc.).

Statement of Conformity

Statement of Conformity

☐ The test results demonstrate that the device is in conformity with the standard(s) listed below[1]:

- Title of Standard:
- FDA Recognition #: *(e.g., 19-4)*
- Options Selected
  - ☐ Standard included no options
  - ☐ Standard included options

    List of options selected in standard (e.g., clause 5.3 permits modified test conditions if ambient temperature cannot be maintained).
- Testing Laboratory Name: *(e.g., Testing Laboratory ABC)*
- Testing Location(s): *(e.g., 1234 Example Road, Silver Spring, MD 20993)*
- Testing Date(s): *(e.g., Sep 1, 2020 – Sep 15, 2020)*
- Supplemental Documentation *(Refer to Section V.C. of this guidance for specific recommendations)*:
  - ☐ Supplementary documentation is not included
  - ☐ Supplementary documentation is included at the following location within the submission, and I have checked that there are no differences regarding protocol and data between the testing conducted and the supplemental documentation: *(e.g., Appendix A of this premarket submission)*

[1] See section 514(c)(3)(A)(i) of the FD&C Act, cited in Section IV.A.(3)(f) of FDA's guidance Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Device.

Limitations on Validity of DOC and Signature

<Repeat for each standard in DOC>

Limitations on Validity of DOC

Description of any limitation on the validity of the DOC (e.g., how long the declaration is valid, what was tested, or concessions made about the testing outcomes

Signature

Printed name: _____

Function within entity responsible for DOC:

_____

Signature Date

“General Use” of Standards

- May cite any consensus standard
- Should include complete test reports
- Considerations:
  - If modifications not referenced or permitted in standard, should include complete test reports
  - When in doubt, ask FDA review team!

Supplemental Documentation

Supplemental Documentation

Standard Type		Complete Test Report Needed?	Supplemental Documentation Needed (ISO/IEC 17050-2)?
Design		No	No
Test Method	**Acceptance Criteria**		
Included	Not Included	No	Yes, Criteria/Summary Results
Not Included	Included	No	Yes
Included	Included	No	No
Not Included	Not included	Yes	Complete Test Report

Supplemental Documentation

Standard Type	Complete Test Report Needed?	Supplemental Documentation Needed (ISO/IEC 17050-2)?
Design	No	No

Supplemental Documentation

Test Method	Acceptance Criteria	Complete Test Report Needed?	Supplemental Documentation Needed (ISO/IEC 17050-2)?
Included	Not Included	No	Yes, Criteria/Summary Results
Not Included	Included	No	Yes
Included	Included	No	No
Not Included	Not included	Yes	Complete Test Report

Supplemental Documentation

Test Method	Acceptance Criteria	Complete Test Report Needed?	Supplemental Documentation Needed (ISO/IEC 17050-2)?
Included	Not Included	No	Yes, Criteria/Summary Results
Not Included	Included	No	Yes
Included	Included	No	No
Not Included	Not included	Yes	Complete Test Report

Supplemental Documentation

Test Method	Acceptance Criteria	Complete Test Report Needed?	Supplemental Documentation Needed (ISO/IEC 17050-2)?
Included	Not Included	No	Yes, Criteria/Summary Results
Not Included	Included	No	Yes
Included	Included	No	No
Not Included	Not included	Yes	Complete Test Report

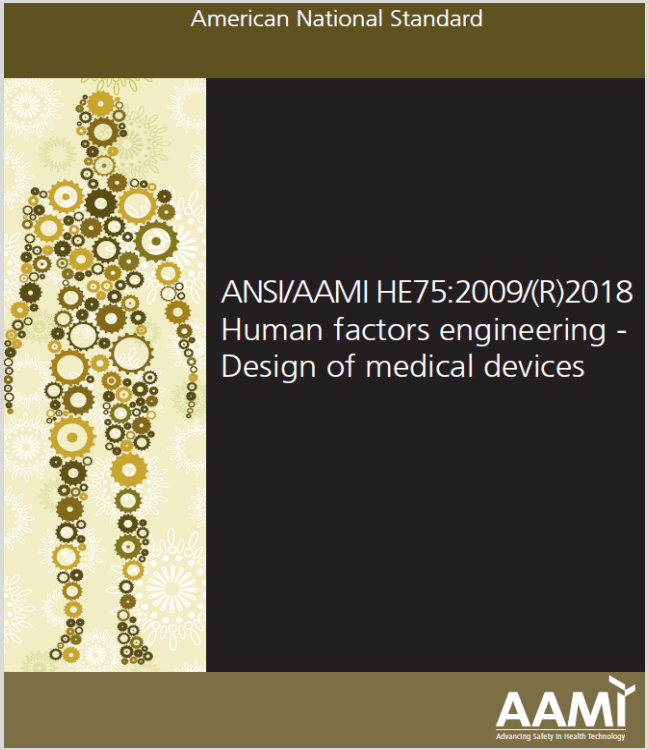
Supplemental Documentation

Test Method	Acceptance Criteria	Complete Test Report Needed?	Supplemental Documentation Needed (ISO/IEC 17050-2)?
Included	Not Included	No	Yes, Criteria/Summary Results
Not Included	Included	No	Yes
Included	Included	No	No
Not Included	Not included	Yes	Complete Test Report

Supplemental Documentation

- Supplemental documentation is needed when:
  - Standard has neither test method nor prespecified acceptance criteria
  - Deviations or adaptations have been made to recognized standard
- Provide complete test report as supplemental documentation
- Note: If elect “General Use”, additional documentation may be needed

ANSI/AAMI HE75:2009(R)28
Not FDA-recognized: *Section 9: Usability testing*



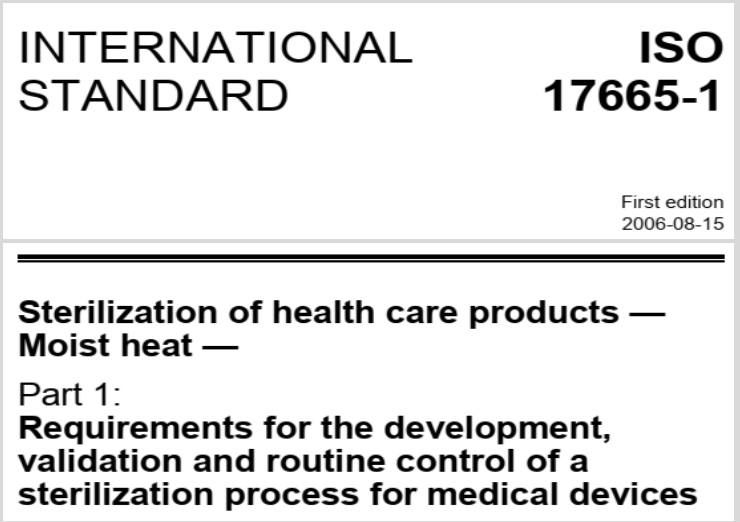
FDA Human Factors Guidance

Section	Contents
1	Conclusion
2	Descriptions of intended device users, uses, use environments, and training
3	Description of device user interface
4	Summary of known use problems
5	Analysis of hazards and risks associated with use of device
6	Summary of preliminary analyses and evaluations
7	Description of categorization of critical tasks
8	Details of human factors validation testing

FDA Guidance: *Applying Human Factors & Usability Engineering to Medical Devices*

When Supplemental Documentation is NOT Needed

- Design standard is cited
- Standard includes *both:*
  - test method and
  - pre-specified performance limit



INTERNATIONAL STANDARD

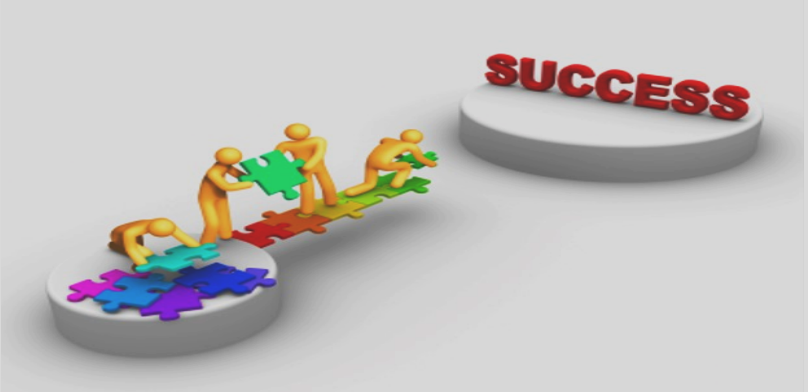
ISO 17665-1

First edition
2006-08-15

Sterilization of health care products — Moist heat —

Part 1:
Requirements for the development, validation and routine control of a sterilization process for medical devices

Helpful Tips for Using Standards in a Submission



What to Avoid

- Inappropriate use of consensus standards
  - Not applicable to your device or intended use
  - Not knowing Extent of Recognition (complete or partial)

- Inappropriate use of a declaration of conformity
  - Citing non-recognized standards (such as older, previous versions)
  - Deviations from recognized standards
  - Using DOCs without appropriate supplemental documentation

What to Avoid

- Assuming that use of consensus standards satisfies ALL submission questions
- Not checking relevant regulation/guidance for additional requirements
- FDA Form 3654: Standards Data Report for 510(k)s; no longer available!

Summary

- How to use standards in device submissions
- How DOCs improve device review
- Use of supplemental documentation
- Helpful tips for using standards and DOCs in submissions

Resources

- **Standards & Conformity Assessment Program (S-CAP)**
  www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/
- **FDA Recognized Consensus Standards Database**
  www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm
- **Device Advice: Comprehensive Regulatory Assistance**
  www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance
- **CDRH Learn: How to Study and Market Your Device: Standards**
  www.fda.gov/training-and-continuing-education/cdrh-learn#collapseTwo

Guidances

- **Appropriate Use of Voluntary Consensus Standards in Premarket Submission for Medial Devices**
  www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices

- **Recognition and Withdrawal of Voluntary Consensus Standards**
  www.fda.gov/regulatory-information/search-fda-guidance-documents/recognition-and-withdrawal-voluntary-consensus-standards

Contact: CDRHStandardsStaff@fda.hhs.gov

Industry Education: Three Resources for You

1. **CDRH Learn: Multi-Media Industry Education**
   - Over 200 modules
   - Videos, audio recordings, power point presentations, software-based "how to" modules
   - Mobile-friendly: access CDRH Learn on your portable devices

   www.fda.gov/CDRHLearn

2. **Device Advice: Text-Based Education**
   - Comprehensive regulatory information on premarket and postmarket topics

   www.fda.gov/DeviceAdvice

3. **Division of Industry and Consumer Education (DICE)**
   - Contact DICE if you have a question
   - Email: **DICE@fda.hhs.gov**
   - Phone: 1(800) 638-2041 or (301) 796-7100 (Hours: 9 am-12:30 pm; 1 pm-4:30pm EST)
   - Web: **www.fda.gov/DICE**

Your Call to Action

- Put standards to work
  - Use FDA-recognized standards in your submissions
- Make sure your documentation is complete
  - Know when you need DOCs and supplement documentation
- Participate in standards development!


FDA
U.S. FOOD & DRUG
ADMINISTRATION