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ANSI/AAMI/ISO
17665-1:2006 (R2013)
Sterilization of health
care products - Moist

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Requirements for the development, validation, and routine control of a sterilization process for medical devices. Specifies requirements for the development, validation, and routine control of a moist heat sterilization process for medical devices.

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Sterilization of ...

AAMI/ISO 17665-1

specifies requirements for the development, validation and routine control of a moist heat sterilization process for medical devices used in any facility that manufactures or reprocesses medical devices. Available for Subscriptions. Content Provider. Association for the Advancement of Medical Instrumentation [AAMI]

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**ANSI/AAMI/ISO
17665-1:2006 -
Sterilization of
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1.1.1 This part of ISO 17665 specifies requirements for the development, validation and routine control of a moist heat sterilization process for medical devices. NOTE Although the scope of this part of ISO 17665 is limited to medical

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devices, it specifies requirements and provides guidance that may be applicable to other health care products.

ISO 17665-1:2006(en), Sterilization of health care ...

ISO 17665-1 was prepared by Technical Committee ISO/TC 198, Sterilization of health care products. This first edition of ISO 17665-1

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2006 Sterilization
cancels and replaces
ISO 11134:1994 and
ISO 13683:1997 both
of which have been
technically revised. ISO
17665 consists of the
following parts, under
the general title
Sterilization of health
care products — Moist

Sterilization of health care products - ANSI Webstore

AAMI. ANSI/AAMI/ISO
17665-1:2006/ (R)2013
- Sterilization of health

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care products-Moist
Heat-Guidance on the
designation of a
medical product to a
product family and
processing category for
steam sterilization.
Edition: 2006.

**ANSI/AAMI/ISO 1766
5-1:2006/(R)2013 -
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ANSI AAMI ISO
17665-1:2006/(R)2013
Sterilization of health
care products -- Moist
heat -- Part 1:
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Requirements for the development, validation, and routine control of a sterilization process for medical devices:
Scope/Abstract.

Recognized Consensus Standards

AAMI/ISO
17665-1:2006, revision
of ANSI/AAMI/ISO
11134:1993)
Sterilization of health
care products - Moist

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2006 Sterilization
Heat - Part 2: Guidance
on the application of
ANSI/AAMI/ISO 17665-1
Approved 18 June 2009
by AAMI Registered 17
May 2009 and
reaffirmed 19 June
2016 by American
National Standards
Institute, Inc.

**Technical
Information Report -
The AAMI Store**

ANSI/AAMI/ISO
17665-1:2006
Sterilization of health

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care products—Moist
heat—Part 1:
Requirements for the
development,
validation, and routine
control of a sterilization
process for medical
devices.

**Steam Sterilization
Validation for
Implementation of
...**

Sterilization of health
care products - Moist
heat - Part 2: Guidance
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ANSI/AAMI/ISO
17665-1. This is a
revision of AAMI
TIR13:1997, and with
ANSI/AAMI/ISO
17665-1:2006, revision
of ANSI/AAMI/ISO
11134:1993. This
Technical Specification
provides general
guidance on the
development,
validation and routine
control of moist heat
sterilization processes
and is intended to
explain the

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2006 Sterilization
requirements set forth
in ISO 17665-1.

**ANSI/AAMI/ISO
TIR17665-2:2009 -
Sterilization of
health ...**

ISO 17665-1:2006
specifies requirements
for the development,
validation and routine
control of a moist heat
sterilization process for
medical devices.. Moist
heat sterilization
processes covered by
ISO 17665-1:2006

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include but are not limited to: saturated steam venting systems; saturated steam active air removal systems;

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17665-1:2006 -
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ANSI/AAMI/ISO TIR
17665-2:2009,
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ANSI/AAMI/ISO
17665-1:2006.

ANSI/AAMI/ISO TIR
17665-3:2014,
Sterilization of health
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Heat - Guidance on the
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Standards**

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17665-1:2006 (R2013)

– Sterilization of health care products – Moist heat – Part1:
Requirements for the development, validation, and routine control of a sterilization process for medical devices

**ISO Health Care
Product Sterilization
... - blog.ansi.org**

Specifies general guidance on the development,

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validation and routine control of moist heat sterilization processes and is intended to explain the requirements set forth in ISO 17665-1.

General Product Information - (Show below) - (Hide below)

**AAMI ISO TIR
17665-2 : 2009 |
STERILIZATION OF
HEALTH CARE ...**

ansi/aami/iso
tir13004:2013 (r2016)

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Sterilization of health care products -
Radiation -
Substantiation of a selected sterilization dose: Method VDmaxSD This Technical Specification describes a method for substantiating a selected sterilization dose of 17.5, 20, 22.5, 27.5, 30, 32.5 or 35 kGy that achieves a sterility assurance level (SAL) of 10 ...

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TIR13004:2013

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Sterilization of ...

ISO 17665-1 First

edition 2006-08-15

Sterilization of health

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heat - Part :

Requirements for the

development,

validation, and routine

control of a sterilization

process for...

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Consensus

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The adoption of ISO
Technical Specification
(TS) 17665-3, as an
AAMI Technical
Information Report was
initiated by the AAMI
Radiation Sterilization
Working Group, which
also functions as the
U.S. Technical Advisory
Group to the relevant
work in the
International

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Organization for
Standardization (ISO).

U.S. representatives
from the AAMI

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Guidance on the
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Specification provides
general guidance on

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