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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.

**ANSI/AAMI/ISO 17665-1:2006  
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## **ANSI/AAMI/ISO 17665-1:2006 -- Sterilization of health care ...**

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

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part of ISO 17665 is limited to medical 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

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health care products. This first edition of ISO 17665-1 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**

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The ISO 17665 series was developed by ISO Technical Committee 198 to fill a need for an international standard for moist heat sterilization of health care products. The standard combines and updates two separate ISO standards, ISO 11135:1993 and ISO 13683:1997, and also supersedes AAMI TIR13:1997,

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control of a sterilization process for...

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## **Recognized Consensus Standards**

ANSI/AAMI/ISO TIR17665-2:2009 (R2016)

- Sterilization of health care products -  
Moist Heat - Part 2: Guidance on the  
application of ANSI/AAMI/ISO 17665-1.

ANSI/AAMI/ISO TIR17665-3:2014 (R2016)

- Sterilization of health care products -  
Moist Heat - Guidance on the  
designation of a medical product to a

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## **ISO Health Care Product Sterilization ... - [blog.ansi.org](http://blog.ansi.org)**

Sterilization of health care products -  
Moist heat - Part 2: Guidance on the  
application of ANSI/AAMI/ISO 17665-1.  
This is a revision of AAMI TIR13:1997,  
and with ANSI/AAMI/ISO 17665-1:2006,

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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 requirements set forth in ISO 17665-1.

**ANSI/AAMI/ISO TIR17665-2:2009 -**



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## **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 include but are not limited to: saturated steam venting systems; saturated steam

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active air removal systems; air steam mixtures; water spray;

## **ISO - ISO 17665-1:2006 -**

### **Sterilization of health care ...**

ANSI AAMI ISO 17665-1:2006/(R)2013  
Sterilization of health care products --  
Moist heat -- Part 1: Requirements for  
the development, validation, and routine

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control of a sterilization process for  
medical devices: Scope/Abstract.

## **Recognized Consensus Standards**

ANSI/AAMI/ISO TIR 17665-2:2009,  
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Moist heat - Part 2: Guidance on the  
application of ANSI/AAMI/ISO  
17665-1:2006. ANSI/AAMI/ISO TIR

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17665-3:2014, Sterilization of health care products - Moist Heat - Guidance on the designation of a medical product to a product family and processing category for steam ...

## **Recognized Consensus Standards**

buy aami iso tir 17665-2 : 2009  
sterilization of health care products -

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moist heat - part 2: guidance on the  
application of ansi/aami/iso 17665-1  
from sai global

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

ISO 17665-1 First edition 2006-08-15  
Sterilization of health care products -  
Moist heat - Part : Requirements for the

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development, validation, and routine control of a sterilization process for...

## **Recognized Consensus Standards**

European standards, International Organization for Standardization (ISO) standards, and U.S. industrial standards, including EN285, HTM 2010, and ANSI/AAMI/ISO 17665, do require that

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these measurements be made as part of qualification of a steam sterilizer and during ongoing periodic validations.

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

This standard has been revised by ISO 17665-1:2006 Abstract Specifies requirements for the use of moist heat in

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sterilization process development,  
validation of the sterilization process  
and control of routine sterilization.

## **ISO - ISO 11134:1994 - Sterilization of health care ...**

Sterilization of health care products -  
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application of ANSI/AAMI/ISO 17665-1



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This Technical Specification provides general guidance on the development, validation and routine control of moist heat sterilization processes and is intended to explain the requirements set forth... TIR17665-2 January 1, 2009

## **AAMI TIR17665-2 - Sterilization of health care products ...**

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ANSI/AAMI/ISO TIR17665-2:2009/(R)2016  
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**ANSI/AAMI/ISO  
TIR17665-2:2009/(R)2016 -  
Technical ...**

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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 Organization for Standardization (ISO). U.S.

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