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~~ISO 17665 1:2006(en), Sterilization of
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~~The goal of the assessment is to
examine, whether the requirements of~~

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ISO 17665-1 are fulfilled, or the satisfactory sterilization with moist heat is evidenced in any other way. Any alternatively allowed procedure designated as such by the ISO 17665-1 shall be accepted.

~~Sterilization of health care products—~~ Moist heat

ISO/TS 17665-2:2009 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. The guidance given in this Technical Specification is provided to promote good practice related to moist heat sterilization processes and to ...

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~~ISO ISO/CD 17665.2 Sterilization of
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ISO 17665 consists of the following
parts, under the general title
Sterilization of health care products —
Moist heat: □ Part 1: Requirements for
the development, validation and routine
control of a sterilization process for
medical devices □ Part 2: Guidance on
the application of ISO 17665-1 This is a
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~~ISO ISO/TS 17665 2:2009 Sterilization
of health care ...~~

BS EN ISO 17665-1:2006 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 ISO 17665 1:2006 Sterilization of health care ...~~

ISO 17665 Steam Sterilization for Medical Devices. Steam Sterilization is a simple yet very effective decontamination method. Sterilization is achieved by exposing products to saturated steam at high temperatures (121°C to 134°C).

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ISO 17665-1 was prepared by Technical Committee ISO/TC 198, Sterilization of 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

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ISO/CD 17665.2 Sterilization of health care products — Moist heat — Requirements for the development, validation and routine control of a sterilization process for medical devices.

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ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). ... ISO 17665 consists of the following parts, under the general title Sterilization of health care products ? ... Introduction. A sterile medical device is one which is free of viable microorganisms ...

~~TECHNICAL ISO/TS SPECIFICATION 17665-2~~

ISO/TS 17665-3:2013 provides guidance about the attributes of a medical device to be considered by the user when assigning a medical device to a product family for the purpose of identifying and aligning it to a processing category for a specific moist heat sterilization process.

~~BS EN ISO 17665 1:2006—Sterilization of health care ...~~

This part of ISO 17665 specifies

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

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according to ISO 17665-1. NOTE 1 The structure of the main body of this ISO Technical Specification (Clauses 1 to 12) corresponds to the structure of ISO 17665-1, so that the guidance given under a particular clause or subclause of this part of ISO 17665 applies to the requirements given in the corresponding clause or subclause of ISO 17665-1.

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