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~~ISO — ISO 17665-1:2006 —
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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

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

ISO/CD 17665.2 Sterilization
of health care products –
Moist heat – Requirements
for the development,

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validation and routine
control of a sterilization
process for medical devices.
General information Status :
Deleted. Edition : 1
Technical Committee: ISO/TC
198. Sterilization of health
care products. ICS :

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11.080.01 Sterilization and
disinfection in general.
Life cycle. A standard is
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~~ISO - ISO/CD 17665.2 -
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ISO/TS 17665-2:2009 ISO specifies requirements for the development, validation and routine control of a moist heat sterilization process for medical devices. We recommend that you check the website of the

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international document
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~~ISO 17665-2 PDF - PDF Result
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libro ... 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

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have been technically revised. ISO 17665 consists of the following parts, under the general title Sterilization of health care products ...

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BS EN ISO 17665 sets out the requirements to ensure best practice steam sterilisation of medical equipment. By following this standard's guidelines, the steam sterilisation process is more likely to produce

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sterile medical instruments
on treatment and improve
overall quality control.

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

Compared with the previous

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versions, DIN 58946-6 and EN 554, the scope of ISO 17665-1 has been extended and now also includes the requirements for the design of sterilization processes. This checklist shall be used for assessment of operators

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of the corresponding
sterilization facilities.

~~410 07e Checklist~~

~~Sterilization Moist Heat~~

~~ISO 17665-1~~

ISO/TS 17665-2:2009 provides
general guidance on the

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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

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promote good practice
related to moist heat
sterilization processes and
to assist those developing
and validating a moist ...

~~ISO — ISO/TS 17665-2:2009 —
Sterilization of health care~~

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...

Scope • This part of ISO 17665 specifies requirements for the development, validation and routine control of a moist heat sterilization process for medical devices.

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~~Standardization of Moist
Heat Expert's Congress SBM~~

~~...~~

ISO 17665 describes
requirements that, if met,
will provide a moist heat
sterilization process

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intended to sterilize medical devices, which has appropriate microbicidal activity. Furthermore, compliance with the requirements ensures this activity is both reliable and reproducible so that

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predictions can be made,
with

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

The guidance given in this
Technical Specification is
provided to promote good

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practice related to moist heat sterilization processes and to assist those developing and validating a moist heat sterilization process according to ISO 17665-1.

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~~ISO/TS 17665-2:2009~~

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Standardisation~~

Reference number ISO

17665-12006E ISO

2006INTERNATIONAL STANDARD

ISO 17665-1 First edition

2006-08-15 Sterilization of

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health care products Moist
heat Part 1 Requirements for
the development, validation
and routine control of a
sterilization process for
medical devices Strilisation
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validation et le contrle de
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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 Page 9/27. Read Online Iso 17665

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Free control of a sterilization process for medical devices _ Part 2: Guidance on the application of ISO 17665-1 This is a preview ...

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Sterilization of health care
products - Moist heat - Part
1: Requirements for the
design, validation and
routine control of a

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sterilization process for
medical devices 5
Application of the
assessment checklist The
checklist serves for the
evaluation of audit results.
Every audit requirement
should be evaluated

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separately. The evaluation

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5.2.1 EN ISO 17665-1 and
ISO/TS 17665-2 7 5.3

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Validation procedure 8 ...
“Sterile” is defined as “a state that is free of viable microorganisms, including viruses”. But in practice it is not possible to make such an absolute statement, and this can only be viewed as

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an ideal scenario. Therefore the requirements of the European pharmacopoeia are used, i.e. a product is deemed to be ...

~~TESTING, VALIDATION AND
ROUTINE CONTROL OF~~

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