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BSI Standards Publication

## Sterilization - Steam sterilizers - Large sterilizers

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## National foreword

This British Standard is the UK implementation of EN 285:2015+A1:2021. It supersedes BS EN 285:2006+A2:2009 which is withdrawn.

The start and finish of text introduced or altered by amendment is indicated in the text by tags. Tags indicating changes to CEN/CENELEC text carry the number of the CEN/CENELEC amendment. For example, text altered by CEN/CENELEC amendment A1 is indicated by **A1** **A1**.

The UK participation in its preparation was entrusted to Technical Committee CH/198, Sterilization and Associated Equipment and Processes.

A list of organizations represented on this committee can be obtained on request to its committee manager.

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English Version

## Sterilization - Steam sterilizers - Large sterilizers

Stérilisation - Stérilisateurs à la vapeur d'eau - Grands stérilisateurs

Sterilisation - Dampf-Sterilisatoren - Groß-Sterilisatoren

This European Standard was approved by CEN on 15 November 2015 and includes Amendment 1 approved by CEN on 23 May 2021.

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**CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels**

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## European foreword

This document (EN 285:2015+A1:2021) has been prepared by Technical Committee CEN/TC 102 "Sterilizers for medical purposes", the secretariat of which is held by DIN.

This document supersedes A1 EN 285:2015 A1.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by December 2021, and conflicting national standards shall be withdrawn at the latest by June 2022.

This document has been prepared under a standardization request given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Regulation(s).

For relationship with EU Directive(s), see informative Annex ZA, which is an integral part of this document.

This document includes Amendment 1 approved by CEN on 23 May 2021.

The start and finish of text introduced or altered by amendment is indicated in the text by tags A1 A1.

The following amendments have been made in comparison EN 285:2015:

- normative references have been updated and corrected in the normative text;
- note to entry was added to 3.17 and 3.27;
- 6.2 was adopted;
- subclause 6.4.4.2 was added;
- note was added to 8.1.3 and 15.1;
- Annex ZA relationship with the General Safety and Performance Requirements of Regulation (EU) 2017/745 including Tables ZA.1, ZA.2 and ZA.3 was added.

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