

# Biological systems for testing sterilizers and sterilization processes

## Part 1. General requirements

The European Standard EN 866-1 : 1997 has the status of a  
British Standard

ICS 11.080

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# Committees responsible for this British Standard

The preparation of this British Standard was entrusted by Technical Committee LBI/35, Sterilizers, autoclaves and disinfectors, to Subcommittee LBI/35/3, Sterilization indicators, upon which the following bodies were represented:

- ABHI Special Interest Section (Sterilizers and Disinfectors)
- Association of British Healthcare Industries
- BLWA Ltd. (the Association of the Laboratory Supply Industry)
- Department of Health (Medical Devices Agency)
- European Sterilization Packaging Association (UK)
- Medical Sterile Products Association
- Public Health Laboratory Service
- Royal College of Pathologists
- Royal Pharmaceutical Society of Great Britain

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## National foreword

This Part of BS EN 866 has been prepared by Subcommittee LBI/35/3 and is the English language version of EN 866-1 : 1997 *Biological systems for testing sterilizers and sterilization processes — Part 1: General requirements*, published by the European Committee for Standardization (CEN).

### Cross-references

| Publication referred to | Corresponding British Standard                                                                                                                       |
|-------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------|
| EN 550 : 1994           | BS EN 550 : 1994 <i>Sterilization of medical devices — Validation and routine control of ethylene oxide sterilization</i>                            |
| EN 552 : 1994           | BS EN 552 : 1994 <i>Sterilization of medical devices — Validation and routine control of sterilization by irradiation</i>                            |
| EN 554 : 1994           | BS EN 554 : 1994 <i>Sterilization of medical devices — Validation and routine control of sterilization by moist heat</i>                             |
| EN 868-1 : 1997         | BS EN 868 <i>Packaging materials and systems for medical devices which are to be sterilized</i>                                                      |
| EN 1174-1 : 1996        | BS EN 1174 <i>Sterilization of medical devices — Estimation of the population of micro-organisms on product</i><br>Part 1 : 1996 <i>Requirements</i> |
| EN 28601 : 1992         | BS EN 28601 : 1992 <i>Specification for representation of dates and times in information interchange</i>                                             |

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### Summary of pages

This document comprises a front cover, an inside front cover, pages i and ii, the EN title page, pages 2 to 10, an inside back cover and a back cover.



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Descriptors: Medical equipment, sterilizers, bioassay, manufacturing, biological indicators, specifications, preparation, packing, labelling

English version

## Biological systems for testing sterilizers and sterilization processes — Part 1: General requirements

Systèmes biologiques pour l'essai des stérilisateurs  
et les procédés de stérilisation —  
Partie 1: Exigences générales

Biologische Systeme für die Prüfung von  
Sterilisatoren und Sterilisationsverfahren —  
Teil 1: Allgemeine Anforderungen

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**Central Secretariat: rue de Stassart 36, B-1050 Brussels**

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