

Sterilization of medical devices — Requirements for medical devices to be designated “STERILE” —

Part 1: Requirements for terminally sterilized medical devices

The European Standard EN 556-1:2001 has the status of a
British Standard

ICS 11.080.01

National foreword

This British Standard was published by BSI. It is the UK implementation of EN 556-1:2001, including Corrigendum September 2006. It supersedes BS EN 556:1995 which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/67, Sterilization of medical devices.

A list of organizations represented on CH/67 can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

Compliance with a British Standard cannot confer immunity from legal obligations.



This British Standard, having been prepared under the direction of the Health and Environmental Sector Policy and Strategy Committee, was published under the authority of the Standards Policy and Strategy Committee on 11 December 2001

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Amendments issued since publication

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16728 Corrigendum No. 1	31 October 2006	Correction to the note in 4.1 and correction to reference 7 to EN 1441