



INTERNATIONAL STANDARD ISO 14937:2000
TECHNICAL CORRIGENDUM 1

Published 2003-06-01

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION • МЕЖДУНАРОДНАЯ ОРГАНИЗАЦИЯ ПО СТАНДАРТИЗАЦИИ • ORGANISATION INTERNATIONALE DE NORMALISATION

Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices

TECHNICAL CORRIGENDUM 1

Stérilisation des produits de santé — Exigences générales pour la caractérisation d'un agent stérilisant et pour le développement, la validation et la vérification de routine d'un processus de stérilisation pour dispositifs médicaux

RECTIFICATIF TECHNIQUE 1

Technical Corrigendum 1 to ISO 14937:2000 was prepared by Technical Committee ISO/TC 198.

Pages 18 and 19

Subclause D.2.5

Delete existing text of D.2.5 and replace it with the following text:

“D.2.5 If the inactivation of 10^6 microorganisms has been confirmed following D.2.4, determine the extent of treatment for the sterilization process by extrapolation to a predicted probability of a surviving microorganism of 10^{-6} or better, taking into account the nature of the inactivation kinetics effected by the sterilizing agent and the number and resistance of the microorganisms on the biological indicator.