

ISO 14937:2009-10 (E)

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

| Contents | | Page |
|--------------------|--|-------------|
| Foreword | | v |
| Introduction | | vi |
| 1 | Scope | 1 |
| 1.1 | Inclusions | 1 |
| 1.2 | Exclusions | 1 |
| 2 | Normative references | 2 |
| 3 | Terms and definitions | 2 |
| 4 | Quality management system elements | 7 |
| 4.1 | Documentation | 7 |
| 4.2 | Management responsibility | 7 |
| 4.3 | Product realization | 8 |
| 4.4 | Measurement, analysis and improvement -- Control of non-conforming product | 8 |
| 5 | Sterilizing agent characterization | 8 |
| 5.1 | General | 8 |
| 5.2 | Sterilizing agent | 8 |
| 5.3 | Microbicidal effectiveness | 8 |
| 5.4 | Effects on materials | 9 |
| 5.5 | Safety and the environment | 9 |
| 6 | Process and equipment characterization | 9 |
| 6.1 | General | 9 |
| 6.2 | Process characterization | 9 |
| 6.3 | Equipment characterization | 10 |
| 7 | Product definition | 10 |
| 8 | Process definition | 11 |
| 9 | Validation | 12 |
| 9.1 | General | 12 |
| 9.2 | Installation qualification | 12 |
| 9.3 | Operational qualification | 13 |
| 9.4 | Performance qualification | 13 |
| 9.5 | Review and approval of validation | 14 |
| 10 | Routine monitoring and control | 14 |
| 11 | Product release from sterilization | 14 |
| 12 | Maintaining process effectiveness | 15 |
| 12.1 | General | 15 |
| 12.2 | Recalibration | 15 |
| 12.3 | Maintenance of equipment | 15 |
| 12.4 | Requalification | 15 |
| 12.5 | Assessment of change | 15 |

| | |
|--|-----------|
| Annex A (normative) Factors to be considered in selection of microorganisms for demonstrating microbicidal effectiveness | 16 |
| Annex B (normative) Approach 1 -- Process definition based on inactivation of the microbial population in its natural state | 18 |
| Annex C (normative) Approach 2 -- Process definition based on inactivation of reference microorganisms and knowledge of bioburden | 19 |
| Annex D (normative) Approach 3 -- Conservative process definition based on inactivation of reference microorganisms | 20 |
| Annex E (informative) Guidance on application of this International Standard | 22 |
| Bibliography | 36 |