

# DIN EN ISO 14937:2010-03 (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 (ISO 14937:2009)**

---

## Contents

	Page
Foreword .....	4
Introduction .....	5
1 Scope .....	7
1.1 Inclusions .....	7
1.2 Exclusions .....	7
2 Normative references .....	8
3 Terms and definitions .....	8
4 Quality management system elements .....	13
4.1 Documentation .....	13
4.2 Management responsibility .....	13
4.3 Product realization .....	14
4.4 Measurement, analysis and improvement -- Control of non-conforming product .....	14
5 Sterilizing agent characterization .....	14
5.1 General .....	14
5.2 Sterilizing agent .....	14
5.3 Microbicidal effectiveness .....	14
5.4 Effects on materials .....	15
5.5 Safety and the environment .....	15
6 Process and equipment characterization .....	15
6.1 General .....	15
6.2 Process characterization .....	15
6.3 Equipment characterization .....	16
7 Product definition .....	16
8 Process definition .....	17
9 Validation .....	18
9.1 General .....	18
9.2 Installation qualification .....	18
9.3 Operational qualification .....	19
9.4 Performance qualification .....	19
9.5 Review and approval of validation .....	20
10 Routine monitoring and control .....	20
11 Product release from sterilization .....	20
12 Maintaining process effectiveness .....	21
12.1 General .....	21
12.2 Recalibration .....	21
12.3 Maintenance of equipment .....	21

12.4	Requalification .....	21
12.5	Assessment of change .....	21
<b>Annex A (normative)</b>	<b>Factors to be considered in selection of microorganisms for demonstrating microbicidal effectiveness .....</b>	<b>22</b>
<b>Annex B (normative)</b>	<b>Approach 1 -- Process definition based on inactivation of the microbial population in its natural state .....</b>	<b>24</b>
<b>Annex C (normative)</b>	<b>Approach 2 -- Process definition based on inactivation of reference microorganisms and knowledge of bioburden .....</b>	<b>25</b>
<b>Annex D (normative)</b>	<b>Approach 3 -- Conservative process definition based on inactivation of reference microorganisms .....</b>	<b>26</b>
<b>Annex E (informative)</b>	<b>Guidance on application of this International Standard .....</b>	<b>28</b>
<b>Bibliography .....</b>		<b>42</b>
<b>Annex ZA (informative)</b>	<b>Relationship between this European Standard and the Essential Requirements of EU Directive 90/385/EEC on Active Implantable Medical Devices .....</b>	<b>44</b>
<b>Annex ZB (informative)</b>	<b>Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC on Medical Devices .....</b>	<b>45</b>
<b>Annex ZC (informative)</b>	<b>Relationship between this European Standard and the Essential Requirements of EU Directive 98/79/EC on in vitro diagnostic medical devices .....</b>	<b>46</b>