

Contents

Glossary of equivalent standards	v
Committee representation.....	vii
Background of AAMI adoption of ISO 11135-1:2007	x
Foreword.....	xi
Introduction	xii
1 Scope.....	1
2 Normative references	2
3 Terms and definitions.....	3
4 Quality management systems	10
4.1 Documentation	10
4.2 Management responsibility.....	10
4.3 Product realization.....	10
4.4 Measurement, analysis and improvement — Control of nonconforming product.....	11
5 Sterilizing agent characterization.....	11
5.1 Sterilizing agent	11
5.2 Microbicidal effectiveness	11
5.3 Material effects	11
5.4 Environmental considerations	11
6 Process and equipment characterization.....	11
6.1 Process characterization	11
6.2 Equipment characterization	12
7 Product definition	13
7.1 General.....	13
7.2 Product safety and performance.....	13
7.3 Microbiological quality	14
7.4 Documentation	14
8 Process definition	14
9 Validation	15
9.1 Installation qualification	15
9.2 Operational qualification	16
9.3 Performance qualification	16
9.4 Varying load configurations	18
9.5 Review and approval of validation	18
10 Routine monitoring and control	19
11 Product release from sterilization	20
12 Maintaining process effectiveness	21
12.1 General.....	21
12.2 Maintenance of equipment.....	21
12.3 Requalification	21
12.4 Assessment of change.....	22
Annex A (normative) Determination of lethal rate of the sterilization process — Biological indicator/bioburden approach	23

Annex B (normative) Conservative determination of lethal rate of the sterilization process — Overkill approach.....	26
Annex C (informative) General guidance	28
Bibliography	46