ISO 19227:2018-03 (E)

Implants for surgery - Cleanliness of orthopedic implants - General requirements

Contents

Page

Foreword iv

Introduction v

1 Scope 1

2 Normative references 1

3 Termsanddefinitions 1

4 General requirements 3
4.1 Quality management system 3
4.2 Risk management 3
4.3 Design of cleaning process 4
4.4 Validation 5
4.5 Sampling 6
4.6 Manufacturing of test specimens 6
4.7 Testing methods 7

5 Cleanliness evaluation: Test methods and cleanliness acceptance criteria after finalcleaning 7
5.1 General 7
5.2 Visual inspection 8
5.3 Bioburden 8
5.4 Bacterial endotoxins 8
5.5 Organic contaminants 8
5.5.1 General 8
5.5.2 Extraction 9
5.5.3 Detection 9
5.6 Inorganic contaminants 10
5.7 Particulate contamination 10
5.8 Cytotoxicity 11

6 Continuedprocessverification 11

7 Documentation 11

Annex A (informative) Potential sources of harm in a cleaning process 12

Annex B (informative) Relation between cleaning process design, validation and risk management 14

Annex C (informative) Relation between cleaning validation, biological evaluation and sterilization validation 16

Bibliography 17