DIN EN ISO 11737-2:2010-04 (E)

Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process (ISO 11737-2:2009)

Contents

Page

Foreword 3

Introduction 4

1 Scope 5

2 Normative references 5

3 Terms and definitions 5

4 Quality management system elements 7

5 Selection of product 8

6 Methods for performing tests of sterility 9

7 Assessment of method for performing tests of sterility 10

8 Maintenance of the method for performing tests of sterility 10

Annex A (informative) Guidance on tests of sterility performed in validation and maintenance of a sterilization process 11

Bibliography 19

Annex ZA (informative) Relationship between this European Standard and the Essential Requirements of EU Directive 90/385/EEC on Active Implantable Medical Devices 21

Annex ZB (informative) Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC on Medical Devices 22

Annex ZC (informative) Relationship between this European Standard and the Essential Requirements of EU Directive 98/79/EC on in vitro diagnostic medical devices 23