DIN EN ISO 11737-2:2020-07 (E)

Sterilization of health care products - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process (ISO 11737-2:2019)

Contents

Page

European foreword ... 3

Annex ZA (informative) **Relationship between this European Standard and the Essential Requirements of EU Directive 90/385/EEC on active implantable medical devices [OJ L 189] aimed to be covered** ... 4

Annex ZB (informative) **Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC on medical devices [OJ L 169] aimed to be covered** ... 6

Annex ZC (informative) **Relationship between this European Standard and the Essential Requirements of EU Directive 98/79/EC on *in vitro* diagnostic medical devices [OJ L 331] aimed to be covered** ... 8

Annex ZD (informative) **Relationship between this European standard and the General Safety and Performance Requirements of Regulation (EU) 2017/745 aimed to be covered** ... 10

Annex ZE (informative) **Relationship between this European standard and the General Safety and Performance Requirements of Regulation (EU) 2017/746 aimed to be covered** ... 12

Foreword ... 14

Introduction ... 16

1 Scope ... 17

2 Normative references ... 17

3 Terms and definitions ... 17

4 General ... 19

5 Selection of product ... 20

5.1 General ... 20

5.2 Sample item portion (SIP) ... 20

5.3 Packaging of product and sample item portions ... 21

6 Methods for performing tests of sterility ... 21

7 Assessment of the method for performing tests of sterility ... 22

8 Maintenance of the method for performing tests of sterility ... 22

Annex A (informative) **Guidance on tests of sterility performed in validation and maintenance of a sterilization process** ... 23

Annex B (informative) **Typical assignment of responsibilities** ... 30

Bibliography ... 31