DIN EN 556-2:2025-01 (E)

Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 2: Requirements for aseptically processed medical devices

Contents

Page

European foreword ... 3

Introduction ... 4

1 Scope ... 5

2 Normative references ... 5

3 Terms and definitions ... 6

4 Requirements ... 8
4.1 Validation and routine control ... 8
4.2 Compliance ... 11
4.3 Documentation and records ... 11

Annex ZA (informative) **Relationship between this European Standard and the General Safety and Performance Requirements of Regulation (EU) 2017/745 aimed to be covered** ... 12

Annex ZB (informative) **Relationship between this European Standard and the General Safety and Performance Requirements of Regulation (EU) 2017/746 aimed to be covered** ... 14

Bibliography ... 16