

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