

DIN EN 556-2:2015-11 (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	10
4.3 Documentation and records.....	10
Annex ZA (informative) Relationship between this European Standard and the Essential Requirements of EU Directive 90/385/EEC on active implantable medical devices.....	11
Annex ZB (informative) Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC on medical devices.....	12
Annex ZC (informative) Relationship between this European Standard and the Essential Requirements of EU Directive 98/79/EC on <i>in vitro</i> diagnostic medical devices	13
Bibliography	15