

# 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

---

<b>Contents</b>	<b>Page</b>
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
<b>Annex ZA (informative) Relationship between this European Standard and the Essential Requirements of EU Directive 90/385/EEC on active implantable medical devices.....</b>	<b>11</b>
<b>Annex ZB (informative) Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC on medical devices.....</b>	<b>12</b>
<b>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 .....</b>	<b>13</b>
<b>Bibliography .....</b>	<b>15</b>