

# DIN EN 285:2016-05 (E)

## Sterilization - Steam sterilizers - Large sterilizers

---

	Contents	Page
European foreword .....	6	
Introduction .....	8	
1 Scope .....	11	
2 Normative references .....	11	
3 Terms and definitions .....	12	
4 Mechanical components .....	18	
4.1 Dimensions .....	18	
4.2 Materials .....	18	
4.3 Pressure vessel .....	18	
4.3.1 General .....	18	
4.3.2 Double ended sterilizers .....	18	
4.3.3 Test connections .....	19	
4.3.4 Insulation .....	20	
4.4 Framework and panelling .....	21	
4.5 Loading equipment .....	23	
4.6 Transport .....	23	
5 Piping system and components .....	23	
5.1 Pipework and fittings .....	23	
5.2 Steam source .....	23	
5.2.1 Steam supply from a dedicated steam generator .....	23	
5.2.2 Steam supply from a central source .....	24	
5.3 Air filter .....	24	
5.4 Vacuum system .....	24	
6 Measuring system, indicating and recording devices for temperature, pressure, time and status indicators .....	24	
6.1 General .....	24	
6.2 Measuring system .....	24	
6.3 Status indicators .....	27	
6.4 Measuring chains and time equipment .....	27	
6.4.1 Temperature probes .....	27	
6.4.2 Temperature measuring chains for control, recording and indication .....	28	
6.4.3 Pressure transducers .....	28	
6.4.4 Pressure measuring chains for control, recording and indication .....	28	
6.4.5 Time control and indicating equipment .....	29	
6.5 Recording systems .....	29	
6.5.1 General .....	29	
6.5.2 Records .....	29	
6.5.3 Data processing .....	31	
7 Control systems .....	32	
7.1 General .....	32	
7.2 Fault indication system .....	33	
7.3 Software verification and validation .....	34	
8 Performance requirements .....	34	

8.1	Steam penetration .....	34
8.2	Physical parameters .....	35
8.2.1	Temperature characteristics .....	35
8.2.2	Bowie and Dick test .....	37
8.2.3	Air leakage .....	37
8.2.4	Air detector .....	37
8.2.5	Hollow load test .....	37
8.3	Load dryness .....	37
8.3.1	Load dryness, small load, textiles .....	37
8.3.2	Load dryness, full load, textiles .....	38
8.3.3	Load dryness, metal load .....	38
9	Sound power and vibration .....	38
9.1	Sound power .....	38
9.2	Vibration .....	38
10	Rate of pressure change .....	38
11	Safety, risk control and usability .....	39
11.1	Protective measures .....	39
11.2	Risk control, usability .....	40
12	Packaging and marking .....	40
13	Service and working environment .....	41
13.1	General .....	41
13.2	Electrical supply .....	41
13.3	Steam supply to the sterilizer chamber .....	41
13.3.1	Non-condensable gases .....	41
13.3.2	Dryness value .....	41
13.3.3	Superheat .....	41
13.3.4	Contaminants .....	41
13.3.5	Pressure fluctuation .....	42
13.3.6	Feed water .....	42
13.4	Lighting .....	42
13.5	Water, except water specified in 13.3.6 .....	42
13.6	Compressed air .....	43
13.7	Electromagnetic interference .....	43
13.8	Drains .....	43
13.9	Working Environment .....	43
13.10	Service connections .....	43
14	Testing .....	43
14.1	General .....	43
14.2	Calibration .....	45
14.3	Environment .....	45
15	Hollow load test .....	46
15.1	General .....	46
15.2	Apparatus .....	46
15.3	Procedure .....	46
16	Thermometric tests .....	47
16.1	Small load, thermometric .....	47
16.1.1	General .....	47
16.1.2	Apparatus .....	47
16.1.3	Procedure .....	48
16.2	Full load, thermometric .....	50
16.2.1	General .....	50
16.2.2	Apparatus .....	50
16.2.3	Procedure .....	50

17	Bowie and Dick test .....	51
17.1	General .....	51
17.2	Apparatus .....	52
17.3	Procedure .....	52
18	Air leakage test .....	52
18.1	General .....	52
18.2	Apparatus .....	52
18.3	Procedure .....	53
18.3.2	Stabilize the temperature of the sterilizer chamber by carrying out one of the following: ..	53
19	Air detector tests .....	53
19.1	General .....	53
19.2	Air detector, small load .....	53
19.2.1	Apparatus .....	53
19.2.1.7	Connected services complying with Clause 13 .....	54
19.2.2	Procedure .....	54
19.3	Air detector, full load .....	55
19.3.1	Apparatus .....	55
19.3.1.2	Thermometric recording instrument as described in 23.3.4.1 .....	55
19.3.2	Procedure .....	55
19.3.2.13	If the air leakage causes the sterilizer chamber pressure to rise more than 1,1 kPa/min re-adjust the metering device to cause a pressure rise of (1,0 ± 0,1) kPa/min .....	56
19.4	Air detector function .....	56
19.4.1	General .....	56
19.4.2	Apparatus .....	56
19.4.3	Procedure .....	56
20	Load dryness test .....	57
20.1	Load dryness, small load, textiles .....	57
20.1.1	General .....	57
20.1.2	Apparatus .....	57
20.1.3	Procedure .....	57
20.2	Load dryness, full load, textile .....	58
20.2.1	General .....	58
20.2.2	Apparatus .....	58
20.2.3	Procedure .....	58
20.3	Load dryness, metal .....	59
20.3.1	General .....	59
20.3.2	Apparatus .....	59
20.3.3	Procedure .....	59
21	Steam quality test .....	60
21.1	Non-condensable gases .....	60
21.1.1	General .....	60
21.1.2	Apparatus .....	60
21.1.3	Procedure .....	61
21.2	Dryness .....	63
21.2.1	General .....	63
21.2.2	Apparatus .....	63
21.2.3	Procedure .....	64
21.3	Superheat .....	67
21.3.1	General .....	67
21.3.2	Apparatus .....	67
21.3.3	Procedure .....	67
21.4	Sampling of steam condensate .....	69
21.4.1	General .....	69
21.4.2	Apparatus .....	69
21.4.3	Procedure .....	69
22	Rate of pressure change .....	71
22.1	General .....	71

<b>22.2</b>	<b>Apparatus .....</b>	<b>71</b>
<b>22.3</b>	<b>Procedure .....</b>	<b>71</b>
<b>23</b>	<b>Test apparatus, equipment and material .....</b>	<b>71</b>
<b>23.1</b>	<b>Standard test pack .....</b>	<b>71</b>
<b>23.2</b>	<b>Reduced test pack .....</b>	<b>74</b>
<b>23.3</b>	<b>Test instruments .....</b>	<b>75</b>
<b>23.3.1</b>	<b>General .....</b>	<b>75</b>
<b>23.3.2</b>	<b>Pressure instruments .....</b>	<b>75</b>
<b>23.3.3</b>	<b>Temperature instruments .....</b>	<b>76</b>
<b>23.3.4</b>	<b>Recording instruments .....</b>	<b>77</b>
<b>23.4</b>	<b>Full load, textiles .....</b>	<b>78</b>
<b>23.5</b>	<b>Test pack, metal .....</b>	<b>78</b>
<b>23.6</b>	<b>Metering device .....</b>	<b>80</b>
<b>24</b>	<b>Documentation to be supplied with the sterilizer .....</b>	<b>81</b>
<b>25</b>	<b>Information to be supplied with the sterilizer .....</b>	<b>81</b>
<b>Annex A (informative)</b>	<b>Environmental aspects .....</b>	<b>85</b>
<b>Annex B (informative)</b>	<b>Suggested maximum values of contaminants in feed water .....</b>	<b>88</b>
<b>Annex C (informative)</b>	<b>Temperature and time tolerances during the small load thermometric test ...</b>	<b>89</b>
<b>Annex D (informative)</b>	<b>Guidance for installation and operational qualification tests which can be included in the instructions for use supplied with a sterilizer .....</b>	<b>90</b>
<b>Annex E (informative)</b>	<b>Criteria for identifying sterilizers as the same type .....</b>	<b>92</b>
<b>Annex F (normative)</b>	<b>Protective measures .....</b>	<b>93</b>
<b>Annex ZA (informative)</b>	<b>Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC on medical devices .....</b>	<b>95</b>
<b>Bibliography .....</b>		<b>100</b>