

DIN EN 285:2021-12 (E)

Sterilization - Steam sterilizers - Large sterilizers (includes Amendment:2021)

Contents		Page
European foreword		7
Introduction		8
1	Scope	11
2	Normative references	11
3	Terms and definitions	13
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	19
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
19	Air detector tests	53
19.1	General	53
19.2	Air detector, small load	53
19.2.1	Apparatus	53
19.2.2	Procedure	54
19.3	Air detector, full load	55
19.3.1	Apparatus	55
19.3.2	Procedure	55
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
22.2	Apparatus	71
22.3	Procedure	71
23	Test apparatus, equipment and material	71
23.1	Standard test pack	71

23.2	Reduced test pack	74
23.3	Test instruments	75
23.3.1	General	75
23.3.2	Pressure instruments	75
23.3.3	Temperature instruments	76
23.3.4	Recording instruments	77
23.4	Full load, textiles	78
23.5	Test pack, metal	78
23.6	Metering device	80
24	Documentation to be supplied with the sterilizer	81
25	Information to be supplied with the sterilizer	81
Annex A (informative)	Environmental aspects	85
Annex B (informative)	Suggested maximum values of contaminants in feed water	88
Annex C (informative)	Temperature and time tolerances during the small load thermometric test	89
Annex D (informative)	Guidance for installation and operational qualification tests which can be included in the instructions for use supplied with a sterilizer	90
Annex E (informative)	Criteria for identifying sterilizers as the same type	92
Annex F (normative)	Protective measures	93
Annex ZA (informative)	Relationship between this European Standard and the General Safety and Performance Requirements of Regulation (EU) 2017/745 aimed to be covered	95
Bibliography	116