

DIN EN 285:2006-08 (E)

Sterilization - Steam sterilizers - Large sterilizers

Contents		Page
Foreword		4
1	Scope	5
2	Normative references	5
3	Terms and definitions	6
4	Mechanical components	10
5	Process components	13
6	Instrumentation, indicating and recording devices	15
7	Control systems	22
8	Performance requirements	23
9	Sound power	26
10	Rate of pressure change	26
11	Safety	27
12	Marking	27
13	Service and local environment	27
14	Testing	29
15	Microbiological test, rubber load	31
16	Thermometric tests	32
17	Bowie and Dick test	36
18	Air leakage test	37
19	Air detector tests	38
20	Load dryness tests	41
21	Sound power test	44
22	Steam quality tests	45
23	Dynamic sterilizer chamber pressure test	55
24	Test apparatus, equipment and material	56
25	Documentation to be supplied by the manufacturer	64

26	Information to be supplied by the manufacturer	65
	Annex A (informative) Environmental aspects	68
	Annex B (informative) Steam supply; suggested maximum values of contaminants in feed water and condensate	73
	Annex C (informative) Recommended materials	74
	Annex D (informative) Temperature and time tolerances during the small load thermometric test ...	77
	Annex E (informative) Guidance for installation and operational qualification tests to be included in the instructions for use supplied with a sterilizer	78
	Annex F (informative) Criteria for identifying sterilizers as the same type	80
	Annex ZA (informative) Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC on medical devices	81
	Bibliography	82