

DIN EN ISO 15883-1:2014-10 (E)

Washer-disinfectors - Part 1: General requirements, terms and definitions and tests (ISO 15883-1:2006 + Amd 1: 2014) (includes Amendment A1:2014)

Contents		Page
Introduction		6
1	Scope	7
2	Normative references	7
3	Terms and definitions	8
4	Performance requirements	14
4.1	General	14
4.2	Cleaning	15
4.3	Disinfection	16
4.4	Rinsing	17
4.5	Drying	17
4.6	Process chemicals	18
5	Mechanical and process requirements	18
5.1	Materials, design and manufacture/construction	18
5.2	Safety	19
5.3	Calorifiers and tanks	20
5.4	Loading and unloading doors and their controls	21
5.5	Pipework and fittings	23
5.6	Spray systems	23
5.7	Dosing systems	24
5.8	Load temperature protection	24
5.9	Process temperature control limits	25
5.10	Switches, gauges and indicating devices	26
5.11	Process verification	26
5.12	Instrumentation and controls	27
5.13	Temperature indicating systems	28
5.14	Pressure indicating systems	29
5.15	Timing equipment	29
5.16	Operating cycle indicating equipment	29
5.17	Recording instruments (if fitted)	29
5.18	Control systems	31
5.19	Override of automatic control	32
5.20	Microprocessor control systems	33
5.21	Access to software	33
5.22	Fault indication systems	33
5.23	Water supply	34
5.24	Venting and drainage systems	34
5.25	Drainage	35
5.26	Air filters installed within the WD	35
5.27	Load handling and supports for use within the WD	35
5.28	Trolleys	36
5.29	Environment	37
6	Testing for conformity	37
6.1	General	37
6.2	Test equipment	40
6.3	Tests on doors, interlocks and fault indications	41

6.4	Tests on water quality and water volume	43
6.5	Tests on pipework	45
6.6	Tests on instrumentation fitted to the WD	47
6.7	Tests on load carriers	48
6.8	Thermometric tests	49
6.9	Chemical dosing tests	52
6.10	Tests of cleaning efficacy	53
6.11	Tests of air quality	54
6.12	Load dryness test	55
6.13	Automatic control test	55
7	Documentation	56
8	Information to be supplied by the manufacturer	56
8.1	General	56
8.2	Before delivery of the WD and for installation	57
8.3	At delivery of the WD	58
9	Marking, labelling and packaging	59
9.1	Marking and labelling	59
9.2	Packaging	59
10	Information to be requested from the purchaser by the supplier of the WD	60
	Annex A (informative) Test programme	61
	Annex B (informative) A0 concept -- Comparative lethality of moist heat processes	65
	Annex C (normative) Test methods for the detection and assessment of residual proteinaceous contamination	69
	Annex D (normative) Microbiological recovery medium for estimation of bacterial contamination of water	74
	Annex ZA (informative) Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC on medical devices	75
	Bibliography	79