

# DIN EN ISO 15883-4:2019-06 (E)

## Washer-disinfectors - Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes (ISO 15883-4:2018)

---

<b>Contents</b>		<b>Page</b>
European foreword .....		5
<b>Annex ZA (informative) Relationship between this European Standard and the essential requirements of Directive 93/42/EEC [OJ L 169] aimed to be covered .....</b>		<b>7</b>
<b>Foreword .....</b>		<b>10</b>
<b>Introduction .....</b>		<b>11</b>
<b>1</b>	<b>Scope .....</b>	<b>12</b>
<b>2</b>	<b>Normative references .....</b>	<b>12</b>
<b>3</b>	<b>Terms and definitions .....</b>	<b>13</b>
<b>4</b>	<b>Performance requirements .....</b>	<b>16</b>
4.1	General .....	16
4.2	Systems for leak testing .....	18
4.3	Cleaning .....	20
4.3.1	General .....	20
4.3.2	Flushing .....	20
4.3.3	Washing .....	20
4.3.4	Post-washing rinsing .....	20
4.3.5	Determination of cleaning efficacy .....	21
4.4	Disinfecting .....	21
4.4.1	General .....	21
4.4.2	Efficacy of the disinfectant .....	21
4.4.3	Temperature .....	22
4.4.4	Process monitoring .....	22
4.4.5	Disinfectant use .....	22
4.5	Final rinsing .....	23
4.6	Purging to remove rinse water .....	23
4.7	Drying .....	24
4.8	Self-disinfection .....	24
4.9	Water treatment equipment .....	25
4.9.1	General .....	25
4.9.2	Disinfection of water treatment equipment .....	25
4.9.3	Maintenance of piping .....	26
<b>5</b>	<b>Mechanical and process requirements .....</b>	<b>26</b>
5.1	Materials – Design, manufacture and construction .....	26
5.2	Device channel irrigation system .....	27
5.2.1	General .....	27
5.2.2	Verification of device channel irrigation by the automatic controller .....	28
5.3	Venting and drainage systems .....	28
5.4	Temperature control .....	28
5.4.1	General .....	28
5.4.2	Temperature control of the washing stage .....	29
5.4.3	Temperature control of the disinfection stage .....	29
5.4.4	WD with a minimum operating temperature for the washing and/or disinfection stage .....	29
5.5	Process chemicals .....	29
5.6	Process verification .....	29
5.7	Dosing systems .....	30
<b>6</b>	<b>Testing for conformity .....</b>	<b>30</b>
6.1	General .....	30
6.2	Test equipment .....	30

6.2.1	General.....	30
6.2.2	Pressure measurement.....	30
6.2.3	Flow measurement.....	30
6.3	Water used for final rinsing.....	31
6.3.1	Principle.....	31
6.3.2	Material/procedure.....	31
6.3.3	Results/acceptance criteria.....	31
6.4	Hardness of water used during type testing.....	31
6.4.1	Principle.....	31
6.4.2	Material.....	31
6.4.3	Procedure.....	32
6.5	Leak test.....	32
6.5.1	Principle.....	32
6.5.2	Material.....	32
6.5.3	Procedure.....	32
6.5.4	Results/acceptance criteria.....	33
6.6	Channels non-obstruction test.....	35
6.6.1	Principle.....	35
6.6.2	Material.....	35
6.6.3	Procedure.....	36
6.6.4	Results/acceptance criteria.....	36
6.7	Channels non-connection test.....	36
6.7.1	Principle.....	36
6.7.2	Material.....	37
6.7.3	Procedure.....	37
6.7.4	Result/acceptance criteria.....	37
6.8	Load dryness.....	37
6.8.1	Principle.....	37
6.8.2	Material.....	37
6.8.3	Exterior surface drying.....	37
6.8.4	Channel drying.....	38
6.9	Thermometric tests.....	38
6.9.1	Test for chamber and load temperature during operating cycle.....	38
6.9.2	Test for operating cycle temperature limits on washing and chemical disinfection stages.....	39
6.10	Chemical dosing tests for single-dose containers.....	39
6.10.1	Principle.....	39
6.10.2	Material.....	39
6.10.3	Procedure.....	39
6.10.4	Results/acceptance criteria.....	40
6.11	Tests of cleaning efficacy.....	40
6.11.1	General.....	40
6.11.2	Principle.....	40
6.11.3	Material.....	40
6.11.4	Procedure.....	41
6.11.5	Results/acceptance criteria.....	41
6.12	Tests of disinfection efficacy.....	41
6.12.1	General.....	41
6.12.2	Preliminary tests on chemical disinfectants.....	42
6.12.3	Self-disinfection tests.....	44
6.12.4	Test of microbial quality of final rinse water treatment equipment.....	45
6.12.5	Disinfection of liquid transport systems following failure of water treatment equipment.....	45
6.12.6	Chemical disinfection of the load.....	46
<b>7</b>	<b>Documentation and inspection.....</b>	<b>47</b>
<b>8</b>	<b>Information to be supplied by the manufacturer.....</b>	<b>47</b>
<b>9</b>	<b>Marking, labelling and packaging.....</b>	<b>48</b>
<b>10</b>	<b>Information to be requested from the purchaser by the manufacturer.....</b>	<b>48</b>

<b>Annex A</b> (informative) <b>Summary of activities covered by this document</b> .....	<b>49</b>
<b>Annex B</b> (normative) <b>Microbiological testing of the efficacy of chemical disinfection of the load</b> ..	<b>51</b>
<b>Annex C</b> (normative) <b>Summary of test programmes</b> .....	<b>55</b>
<b>Annex D</b> (normative) <b>Methods for microbiological evaluation of disinfection of liquid transport system</b> .....	<b>59</b>
<b>Annex E</b> (normative) <b>Tests for microbial contamination of final rinse water</b> .....	<b>64</b>
<b>Annex F</b> (informative) <b>Additional notes on microbiological testing of chemical disinfection processes</b> .....	<b>66</b>
<b>Annex G</b> (informative) <b>Typical specifications of trumpet valves and connection ports</b> .....	<b>68</b>
<b>Annex H</b> (normative) <b>Establishing endoscope type test groups</b> .....	<b>74</b>
<b>Annex I</b> (informative) <b>Establishing endoscope product families</b> .....	<b>87</b>
<b>Bibliography</b> .....	<b>91</b>