DIN EN ISO 15883-7:2016-10 (E)

Washer-disi nfectors - Part 7: Requirements and tests for washer-disinfectors employing chemical disinfection for non-invasive, non-critical thermolabile medical devices and healthcare equipment (ISO 15883-7:2016)

Contents

Page

European foreword ... **4**

Annex ZA (informative) **Relationship between this European Standard and the essential requirements of Directive 93/42/EEC [OJ L 169] aimed to be covered** ... **6**

Foreword ... **13**

Introduction ... **14**

1 Scope ... **15**

2 Normative references ... **15**

3 Terms and definitions ... **16**

4 Performance requirements ... **16**
4.1 General ... 16
4.2 Cleaning ... 17
4.3 Disinfection ... 17
4.4 Final rinsing ... 19
4.5 Self-disinfection ... 19
4.6 Drying ... 20
4.7 Water treatment equipment ... 20
4.7.1 General ... 20
4.7.2 Disinfection of water treatment equipment ... 20
4.7.3 Maintenance of piping ... 21

5 Mechanical requirements ... **21**
5.1 Materials — Design, manufacture, and assembly ... 21
5.2 Process verification ... 21

6 Testing for conformity ... **21**
6.1 General ... 21
6.2 Test load ... 22
6.2.1 Loading with standard goods ... 22
6.2.2 Loading with special goods ... 22
6.3 Water used for rinsing following disinfection ... 22
6.4 Load dryness ... 22
6.4.1 General ... 22
6.4.2 Procedure ... 22
6.4.3 Results ... 22
6.5 Thermometric tests ... 22
6.5.1 General ... 22
6.5.2 Load temperature test ... 22
6.6 Chemical dosing tests ... 23
6.6.1 General ... 23
6.6.2 Reused process chemicals ... 23
6.7 Tests of cleaning efficacy ... 23
6.7.1 General ... 23
6.7.2 Materials ... 23
6.7.3 Procedure ... 24
6.7.4 Results ... 24

6.8 Test of disinfection efficacy 24
6.8.1 General 24
6.8.2 Preliminary tests on chemical disinfectants 24
6.8.3 Self-disinfection tests 25
6.8.4 Chemical disinfection of the load 26
7 Documentation 26
8 Information to be provided by the manufacturer 26
9 Marking, labelling, and packaging 27
10 Information to be requested from the purchaser by the manufacturer 27
Annex A (normative) **Summary of test programmes 28**
Annex B (normative) **Methods for microbiological evaluation of disinfection of liquid transport system 30**
Annex C (normative) **Tests for microbiological contamination of post-disinfection rinse water 35**
Annex D (normative) **Preparation and evaluation of indicators for microbiological testing of the efficacy of chemical disinfection of the load 37**
Annex E (informative) **Examples of test locations for the tests with biological indicators 40**
Bibliography 44