

# ISO 15883-4:2008-05 (E)

## Washer-disinfectors - Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes

---

| <b>Contents</b>    |   | <b>Page</b> |
|--------------------|---|-------------|
| Foreword .....     |   | v           |
| Introduction ..... |   | vi          |
| <b>1</b>           | <b>Scope .....</b>  | <b>1</b>    |
| <b>2</b>           | <b>Normative references .....</b>   | <b>2</b>    |
| <b>3</b>           | <b>Terms and definitions .....</b>  | <b>2</b>    |
| <b>4</b>           | <b>Performance requirements .....</b>   | <b>3</b>    |
| 4.1                | General .....   | 3           |
| 4.2                | Systems for leak testing .....  | 4           |
| 4.3                | Cleaning .....  | 6           |
| 4.4                | Disinfecting .....  | 7           |
| 4.5                | Final (post-disinfection) rinsing .....   | 9           |
| 4.6                | Purging to remove rinse water .....   | 9           |
| 4.7                | Drying .....  | 9           |
| 4.8                | Self-disinfection .....   | 10          |
| 4.9                | Water treatment equipment .....   | 11          |
| <b>5</b>           | <b>Mechanical and process requirements .....</b>                                | <b>12</b>   |
| 5.1                | Materials Design, manufacture and construction .....                            | 12          |
| 5.2                | Device channel irrigation system .....  | 12          |
| 5.3                | Venting and drainage systems .....  | 13          |
| 5.4                | Temperature control .....   | 14          |
| 5.5                | Process chemicals .....   | 14          |
| 5.6                | Process verification .....  | 14          |
| 5.7                | Dosing systems .....  | 14          |
| <b>6</b>           | <b>Testing for conformity .....</b>   | <b>14</b>   |
| 6.1                | General .....   | 14          |
| 6.2                | Test equipment .....  | 15          |
| 6.3                | Water used for final (post-disinfection) rinsing .....                          | 15          |
| 6.4                | Hardness of water used during type testing .....                                | 15          |
| 6.5                | Leak test .....   | 16          |
| 6.6                | Channels non-obstruction test .....   | 18          |
| 6.7                | Channels non-connection test .....  | 19          |
| 6.8                | Load dryness .....  | 20          |
| 6.9                | Thermometric tests .....  | 20          |
| 6.10               | Chemical dosing tests .....   | 21          |
| 6.11               | Tests of cleaning efficacy .....  | 22          |
| 6.12               | Test of disinfection efficacy .....   | 23          |
| <b>7</b>           | <b>Documentation and inspection .....</b>                                       | <b>27</b>   |
| <b>8</b>           | <b>Information to be supplied by the manufacturer .....</b>                     | <b>27</b>   |
| <b>9</b>           | <b>Marking, labelling and packaging .....</b>                                   | <b>28</b>   |
| <b>10</b>          | <b>Information to be requested from the purchaser by the manufacturer .....</b> | <b>28</b>   |

|  |           |
|--|-----------|
| <b>Annex A (informative) Summary of activities covered by this Part of ISO 15883 .....</b>                         | <b>29</b> |
| <b>Annex B (normative) Microbiological testing of the efficacy of chemical disinfection of the load .....</b>      | <b>31</b> |
| <b>Annex C (informative) Summary of test programmes .....</b>  | <b>34</b> |
| <b>Annex D (normative) Methods for microbiological evaluation of disinfection of liquid transport system .....</b> | <b>35</b> |
| <b>Annex E (normative) Tests for microbial contamination of post-disinfection rinse water .....</b>                | <b>40</b> |
| <b>Annex F (informative) Typical specifications of trumpet valves and connection ports .....</b>                   | <b>41</b> |
| <b>Annex G (informative) Additional notes on microbiological testing of chemical disinfection processes .....</b>  | <b>46</b> |
| <b>Bibliography .....</b>  | <b>48</b> |