



## PRODUCT MANUAL FOR

### Washer-Disinfectors

#### Part 2 Requirements and Tests for Washer-Disinfectors Employing Thermal Disinfection for Surgical Instruments, Anaesthetic Equipment, Bowls, Dishes, Receivers, Utensils, Glassware, etc as per IS/ISO 15883 (Part 2): 2006

विभिन्न उत्पादों के लिए भारतीय मानक ब्यूरो) अनुरूपता मूल्यांकन (विनियम, 2018 की योजना -I के तहत प्रमाणन के संचालन में एकरूपता और पारदर्शिता के लिए इस उत्पाद मैनुअल का उपयोग सभी क्षेत्रीय / शाखा कार्यालयों और लाइसेंसधारियों द्वारा संदर्भ सामग्री के रूप में किया जाएगा। दस्तावेज़ का उपयोग बीआईएस प्रमाणन प्राप्त करने के इच्छुक संभावित आवेदकों द्वारा भी किया जा सकता है।

*This Product Manual shall be used as reference material by all Regional/Branch Offices & licensees to ensure uniformity of practice and transparency in operation of certification under Scheme-I of Bureau of Indian Standards (Conformity Assessment) Regulations, 2018 for various products. The document may also be used by prospective applicants desirous of obtaining BIS certification.*

|    |                                                                  |   |                                                                                                                                                                                                              |
|----|------------------------------------------------------------------|---|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1. | मानक संख्या<br>IS No.                                            | : | IS/ISO 15883 (Part 2): 2006                                                                                                                                                                                  |
|    | शीर्षक<br>Title                                                  | : | Washer-Disinfectors Part 2 Requirements and Tests for Washer-Disinfectors Employing Thermal Disinfection for Surgical Instruments, Anaesthetic Equipment, Bowls, Dishes, Receivers, Utensils, Glassware, etc |
|    | संशोधनों की संख्या<br>No. of amendments                          | : | Nil                                                                                                                                                                                                          |
| 2. | नमूना दिशानिर्देश<br>Sampling Guidelines                         |   |                                                                                                                                                                                                              |
| a) | कच्चा माल<br>Raw material                                        | : | NA                                                                                                                                                                                                           |
| b) | समूहीकरण दिशानिर्देश<br>Grouping Guidelines                      | : | Please refer ANNEX – A                                                                                                                                                                                       |
| c) | नमूने का परिमाण<br>Sample Quantity                               | : | 1 machine                                                                                                                                                                                                    |
|    |                                                                  |   |                                                                                                                                                                                                              |
| 3. | परीक्षण उपकरणों की सूची<br>List of Test Equipment                | : | Please refer ANNEX – B                                                                                                                                                                                       |
|    |                                                                  |   |                                                                                                                                                                                                              |
| 4. | निरीक्षण और परीक्षण की स्कीम<br>Scheme of Inspection and Testing | : | Please refer ANNEX – C                                                                                                                                                                                       |

|                                                                                                              |                                                       |                                                                                                                                                                                                              |                                                                                                               |
|--------------------------------------------------------------------------------------------------------------|-------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------|
| 5.                                                                                                           | एक दिन में संभावित परीक्षण<br>Possible tests in a day | :                                                                                                                                                                                                            | All possible tests as specified IS/ISO 15883-2 and Routine tests as Per Annex – A of IS IS/ISO 15883 (Part 1) |
| 6.                                                                                                           | लाइसेंस का दायरा /Scope of the Licence:               |                                                                                                                                                                                                              |                                                                                                               |
| *License is granted to use Standard Mark as per <i>IS/ISO 15883 (Part 2): 2006</i> with the following scope: |                                                       |                                                                                                                                                                                                              |                                                                                                               |
| Name of the product                                                                                          |                                                       | Washer-Disinfectors Part 2 Requirements and Tests for Washer-Disinfectors Employing Thermal Disinfection for Surgical Instruments, Anaesthetic Equipment, Bowls, Dishes, Receivers, Utensils, Glassware, etc |                                                                                                               |
| Model                                                                                                        |                                                       |                                                                                                                                                                                                              |                                                                                                               |
| Ratings                                                                                                      |                                                       | Rated Voltage .....V (or) Rated Voltage Ranges(s) .....V<br>Frequency .... Hz,<br>Rated current .....A<br>Input Power .....VA (or) .....W                                                                    |                                                                                                               |
| Nature of Supply                                                                                             |                                                       | ac (or) dc                                                                                                                                                                                                   |                                                                                                               |
| Lowest and highest pressure of water and steam (total pressure)                                              |                                                       |                                                                                                                                                                                                              |                                                                                                               |
| Lowest and highest water Temperature (for each type of water)                                                |                                                       |                                                                                                                                                                                                              |                                                                                                               |

**ANNEX -A**

**Grouping Guidelines**

1. Manufacturer shall submit the declaration for each of the parameters as specified in scope of the licence (as per Sl. No. 6 above) of each model of 'Washer-Disinfectors' they intend to cover in the scope of licence.
2. For Grant of Licence/ Change in Scope of Licence, each 'Model' of 'Washer-Disinfectors' is to be tested.
3. During the operation of the Licence, BO shall ensure that all the model(s) covered in the Scope of the Licence are tested in rotation to the extent possible.

**Note 1:** Firm shall submit the Technical description as per Cl. 7 of IS/ISO 15883 (Part 2): 2006 for each of the Model of Washer-Disinfectors.

**Note 2:** Firm shall submit the dimensions and drawing of the Washer-Disinfectors and its chamber.

**Note 3:** Firm shall declare the accessories provided alongwith the Washer-Disinfectors.

**ANNEX- B**  
**LIST OF TEST EQUIPMENTS**  
**(INDICATIVE LIST, FOR GUIDANCE ONLY)**

| Sl. No. | Tests used in with Clause Reference                                                      | Test Equipment                                                                                                                         |
|---------|------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------|
| 1.      | Power Input, 4.11                                                                        | Power Input Test Apparatus/Power Analyzer / Multimeter                                                                                 |
| 2.      | Accessible Parts 5.9.2                                                                   | Test Finger with accessibility test apparatus                                                                                          |
| 3.      | Durability of markings, 7.1.3                                                            | Distilled water, ethanol 96%, Isopropyl alcohol, Stop watch                                                                            |
| 4.      | Earth Leakage Current, 8.7.4.5, Touch Current, 8.7.4.6, Patient Leakage Current, 8.7.4.7 | Figure 13 to Figure 18, Leakage Current Tester, metal foil, Test Pin as per Figure 8 or a particular tool as specified by manufacturer |
| 5.      | Impedance and current carrying capability, 8.6.4                                         | AC/DC voltage source, Multimeter/Earth Resistance Tester                                                                               |
| 6.      | Dielectric Strength, 8.8.3                                                               | High Voltage Tester                                                                                                                    |
| 7.      | Creepage Distances And Air Clearances 8.9                                                | Vernier Caliper, Filler Gauge                                                                                                          |

**Note 1:** The licensee shall maintain a Technical file and Risk Management File as per the provisions of IS/ISO 15883 (Part 1): 2006 for each model in the scope of license.

**Note 2:** The Technical File and Risk Management File shall be maintained by the licensee till the End of Life for each model.

## **ANNEX C**

### **SCHEME OF INSPECTION AND TESTING**

#### **1. QUALITY ASSURANCE PLAN**

- 1.1. It is expected that manufacturers (licensees/applicants) will implement a Quality Assurance Plan i.e. a plan of regular testing and in-process controls, designed to ensure that the product bearing the Standard Mark conforms to all requirements of the Indian Standard.
- 1.2 The manufacturers shall define a Quality Assurance Plan defining the control unit (i.e. lot/batch etc.) and the levels of control (i.e. the frequency and number of samples for conducting the different tests as per the Indian Standard) and submit the same to BIS Branch Office for information. The manufacturer shall comply with the same and maintain test records in accordance with para 2.4.

#### **1.3 RECOMMENDED LEVELS OF CONTROL/CONTROL UNIT:**

- 1.3.1 For the guidance of manufacturers in preparing the Quality Assurance Plan, recommended levels of control are given in Table 1.
- 1.3.2 The manufacturer shall ensure inspection and testing as per the Quality Assurance Plan submitted by them on the whole production of the factory which is covered by this plan. Alternatively, the manufacturer has the option of adherence to the quality plan as per levels of control recommended in column 3 of Table 1.
- 1.4 However, all manufacturers shall ensure compliance of their products to all the requirements of the Indian Standard.

#### **2. ENSURING COMPLIANCE THROUGH TESTING-** It is expected that manufacturers (licensees/applicants) will establish a suitably equipped and staffed in house laboratory (In house testing facility) for testing at least those parameters of the Indian Standard which require routine testing for ensuring quality of the product. This includes in-process controls as may be defined and put in place by the manufacturer and testing parameters/requirements which can only be performed in the factory.

- 2.1 For the guidance of manufacturers, Table 1 giving the recommended levels of control is given below. Column 2 of Table 1 indicates routine tests where test equipment is required in house as “R” or other tests which can be subcontracted as “S”. Subcontracting is permitted to BIS recognized/empanelled laboratory or any other laboratory having valid NABL accreditation as per IS/ISO/IEC 17025.

#### **2.2 For MSME manufacturers, the requirement of maintaining a laboratory/in-house testing facility for routine tests (indicated as “R” in Column 2 of Table 1) is also optional.**

- 2.2.1 MSME manufacturers may utilize common cluster based facilities as per guidelines for the utilization of cluster based test facilities by MSMEs or the provisions of Sharing of testing facilities or get testing done from BIS recognized/empaneled laboratory or any other laboratory having valid NABL accreditation as per IS/ISO/IEC 17025.

**2.3 Large Scale manufacturers shall maintain an in-house laboratory equipped at least with test facilities for routine tests (indicated as “R” in Column 2 of Table 1),** where different tests given in the specification shall be carried out in accordance with the method given in the specification. They shall also implement a calibration plan for the in-house test equipment.

2.3.1 Alternatively, in lieu of an in-house laboratory, large scale manufacturers can also utilize the provisions of Sharing of testing facilities as per the Guidelines for Grant of Licence available on BIS website [www.bis.gov.in](http://www.bis.gov.in). (Under Conformity Assessment>Product Certification Process). Even for subcontracted tests, provisions for sharing of testing facilities can be utilized.

**2.4 TEST RECORDS-** The manufacturers maintaining an in-house laboratory or utilizing common cluster based facilities or shared test facilities shall maintain test records for the tests carried out to establish conformity. For the tests being subcontracted to BIS recognized/empanelled laboratory or any other laboratory having valid NABL accreditation as per IS/ISO/IEC 17025, test reports issued by the laboratories shall be available for inspection by BIS.

**2.5.1 TECHNICAL FILE-** Licencee shall maintain a Technical File for each model being manufactured by them. The Technical file shall be submitted to BIS at the time of Grant of Licence/ inclusion/ surveillance.

**2.5.1.1** The Technical File shall be maintained till the End of Life of the model.

**2.5.1.2** Licencee shall declare the frequency of periodic review of Technical file to BIS and record of review shall be maintained. In case of any change in the Technical file due to any periodic review/ change in the product, the licensee shall inform the same to BIS and submit the copy of the latest version of Technical File to BIS within 30 days of issue of the revised/ modified Technical File.

**2.5.1.3** For changes in the product which shall affect the Scope of the Licence, the modified product shall be treated as a different model and separate Technical File shall be maintained for the same.

**2.5.1.4** The technical file shall consist of the following documents:

- Technical description of the product (as per Cl. 7 of IS/ISO 15883-2)
- Product Manual and/ or Instructions for use;
- Instructions for repair/ service for the product/ components, if required;
- Frequency of periodic repair/ service for the product/ components, if required;
- Conceptual product design and manufacturing drawings and, where appropriate, list of components, electrical circuit design, etc with descriptions and explanations needed for the understanding of these drawings;
- A list of the all Indian/ International standards applied in full or in part during the conformity assessment process with copy of test certificate/ test report;
- Test reports/ Test Certificates and risk assessment file for the product and/ or components as per relevant Clauses of the Indian Standard;
- Copies of conformity assessment documentation for critical product components and accessories;

**2.5.2 RISK MANAGEMENT FILE-** The licensee shall maintain a Risk Management File for each model in the scope of licence as per the requirement of IS/ISO 15883-2. The Risk Management File shall be submitted to BIS at the time of Grant of Licence/Inclusion/Surveillance.

**2.5.2.1** The Risk Management File shall be maintained till the End of Life of each model.

**2.5.2.2** Licencee shall declare the frequency of periodic review of Risk Management File to BIS and record of review shall be maintained. In case of any change in the Risk Management File due to any periodic review/ change in the product, the licensee shall inform the same to BIS and submit the copy of the latest version of Risk Management File to BIS within 30 days of issue of the revised/ modified Technical File.

**3. PACKING AND MARKING** - The Standard Mark as given in the Schedule of the licence shall be incorporated legibly and indelibly on each Washer Disinfectors provided always that the material so marked conforms to each requirement of the specification.

3.1 Marking and labeling shall be done as per Cl. 9.1 of IS/ISO 15883-1.

3.2 Packaging shall be done as per Cl. 9.2 of IS/ISO 15883-1.

**3.3. Additional Marking requirements:** The material shall also be marked with the following additional requirement on each product and packaging:

a) “For BIS certification details please visit [www.bis.gov.in](http://www.bis.gov.in)”

3.4 All the production which conforms to the Indian Standard and covered under the scope of this licence shall be marked with the Standard Mark.

**4. HYGIENIC CONDITIONS (if applicable) – NA.**

**5. REJECTION** - Disposal of non-conforming product shall be done in such a way so as to ensure that there is no violation of provisions of BIS Act,2016.

**TABLE-1**

| (1)          |                                                                        |                    |                                      | (2)                                                                                  | (3)               |                                                                                   |         |
|--------------|------------------------------------------------------------------------|--------------------|--------------------------------------|--------------------------------------------------------------------------------------|-------------------|-----------------------------------------------------------------------------------|---------|
| Test Details |                                                                        |                    |                                      | Test Equipment<br>requirement<br>R: Required (or)<br>S: Sub-contracting<br>permitted | Levels of Control |                                                                                   |         |
| Cl.          | Requirement                                                            | Test Method        |                                      |                                                                                      | No. of Sample     | Frequency                                                                         | Remarks |
|              |                                                                        | Clause             | Reference                            |                                                                                      |                   |                                                                                   |         |
| 4            | Performance Requirements                                               |                    |                                      |                                                                                      |                   |                                                                                   |         |
| 4.1          | General                                                                | 4.1.1 to<br>4.1.6  | IS/ISO 15883-2                       | R                                                                                    | Each WD           |                                                                                   |         |
| 4.2          | Cleaning                                                               | 4.2.1 to<br>4.2.3  | IS/ISO 15883-2<br><br>IS/ISO 15883-5 | R                                                                                    | Each WD           |                                                                                   |         |
| 4.3          | Disinfecting                                                           | 4.3.1 to<br>4.3.4  | IS/ISO 15883-2                       | R                                                                                    | Each WD           |                                                                                   |         |
| 4.4          | Temperature of internal<br>surfaces of processed devices               | 4.4                | IS/ISO 15883-2                       | R                                                                                    | Each WD           |                                                                                   |         |
| 5            | Mechanical and control requirements                                    |                    |                                      |                                                                                      |                   |                                                                                   |         |
| 5.1          | Load connectors                                                        |                    |                                      |                                                                                      |                   |                                                                                   |         |
| 5.1.1        | Connectors for powered<br>devices                                      | 5.1.1              | IS/ISO 15883-2                       | R                                                                                    | Each WD           |                                                                                   |         |
| 5.1.2        | Verification of flow through<br>lumen and powered devices              | 5.1.2.1<br>5.1.2.2 | IS/ISO 15883-2                       | R                                                                                    | Each WD           |                                                                                   |         |
| 5.2          | Control Systems                                                        | 5.2.1 to<br>5.2.3  | IS/ISO 15883-2                       | R                                                                                    | Each WD           |                                                                                   |         |
| 5.3          | Process verification                                                   | 5.3                | IS/ISO 15883-2                       | R                                                                                    | Each WD           |                                                                                   |         |
| 6            | Testing for conformity                                                 |                    |                                      |                                                                                      |                   |                                                                                   |         |
| 6.2          | Tests for soil removal from<br>chamber walls, load carrier<br>and load | 6.10               | IS/ISO 15883-1                       | S                                                                                    | One               | Once in every six month for each type of model<br>manufactured during that period |         |

|       |                                                                                                  |                |                                  |   |                  |                                                                                                        |
|-------|--------------------------------------------------------------------------------------------------|----------------|----------------------------------|---|------------------|--------------------------------------------------------------------------------------------------------|
| 6.3   | Thermostatic Tests                                                                               |                |                                  |   |                  |                                                                                                        |
| 6.3.2 | Load temperature test                                                                            | 6.3.1<br>6.8.2 | IS/ISO 15883-2<br>IS/ISO 15883-1 | S | One              | Once in every six month for each type of model manufactured during that period                         |
| 6.3.3 | Temperature of internal surfaces of devices                                                      | 6.3.3          | IS/ISO 15883-2                   | S | One              |                                                                                                        |
|       | Performance Requirements                                                                         |                |                                  |   |                  |                                                                                                        |
|       | Marking and documentation                                                                        | 5              | IEC 61010-2-040                  | R | Each WD          |                                                                                                        |
|       | Protection against electric shock                                                                | 6              | IEC 61010-2-040                  | S | One              | Once in every six month for each model manufactured during that period                                 |
|       | Protection against mechanical HAZARDS and against HAZARDS related to mechanical functions        | 7              | IEC 61010-2-040                  | S | One              |                                                                                                        |
|       | Resistance to mechanical stresses                                                                | 8              | IEC 61010-2-040                  | S | One              | Once in every six month for each model manufactured during that period                                 |
|       | Protection against the spread of fire                                                            | 9              | IEC 61010-2-040                  | S | One              |                                                                                                        |
|       | Equipment temperature limits and resistance to heat                                              | 10             | IEC 61010-2-040                  | S | One              |                                                                                                        |
|       | Protection against HAZARDS from fluids and solid foreign objects                                 | 11             | IEC 61010-2-040                  | S | One              |                                                                                                        |
|       | Protection against radiation, including laser sources, and against sonic and ultrasonic pressure | 12             | IEC 61010-2-040                  | S | One              | Once in every six month for each model manufactured during that period                                 |
|       | Protection against liberated gases, substances, explosion and implosion                          | 13             | IEC 61010-2-040                  | S | One              |                                                                                                        |
|       | Components and subassemblies                                                                     | 14             | IEC 61010-2-040                  | S | Each consignment | No further testing is required if accompanied with Test Certificate or covered in Risk Management file |
|       | Protection by interlocks                                                                         | 15             | IEC 61010-2-040                  | S | One              | Once in every six month for each model manufactured during that period                                 |

|   |                                          |    |                 |   |         |                                                                                                              |  |
|---|------------------------------------------|----|-----------------|---|---------|--------------------------------------------------------------------------------------------------------------|--|
|   | HAZARDS resulting from application       | 16 | IEC 61010-2-040 | R | Each WD | Testing and assessment of the product to be done as specified in the Technical File and Risk Assessment File |  |
|   | RISK assessment                          | 17 | IEC 61010-2-040 | R | Each WD |                                                                                                              |  |
|   | <b>Emissions</b>                         |    |                 |   |         |                                                                                                              |  |
|   | Electromagnetic Compatability            |    | IEC 61326-1     | S | One     | Once in every three years for each model manufactured during that period                                     |  |
| 7 | Information supplied by the Manufacturer | 7  | IS/ISO 15883-2  | R | Each WD |                                                                                                              |  |