



Endoscope
Process Wheel

Pure Technology

ISO 15883 COMPLIANCE? IT'S NOT A SIMPLE YES OR NO ANSWER.

ISO 15883 relates to a series of standards that specify the required performance levels of **Washer-Disinfectors (WDs)**. A flexible endoscope washer should meet the criteria specified in Part 1 and 4 in conjunction with the selected test soil(s) described in the Technical Specification Part 5. The ADAPTASCOPE™ Washer-Disinfecter and ASP's detergent and biocides combinations are compliant with the ISO 15883* standards.



Protecting Lives Against Infection™

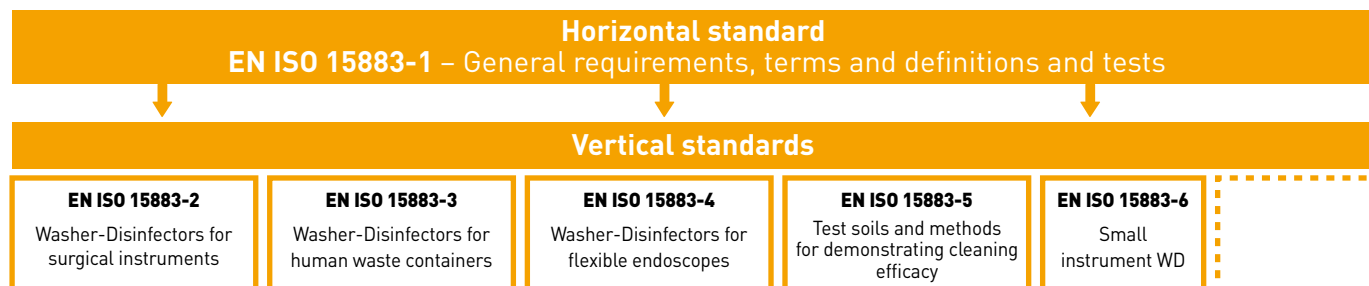
Think solution, not product



Endoscope
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ISO 15883 COMPLIANCE? IT'S NOT A SIMPLE YES OR NO ANSWER.

ISO 15883 relates to a series of standards that specify the required performance levels of Washer-Disinfectors (WDs). Part 1 describes the general requirements, tests and terms and definitions which serve as the basis to support the scientific requirements detailed in Part 2, 3 and 4. For WDs of thermolabile flexible endoscopes, the selected test soil(s) specified in Part 5 must be tested against the procedures in Part 1 and 4.



ISO 15883-1 - General requirements, terms and definitions and tests

Part 1 specifies the general performance requirements for WDs and their accessories that are intended to be used for cleaning and disinfection of re-usable medical devices. It also specifies the methods and instrumentation required for validation, routine control and monitoring and re-validation, periodically and after essential repairs. Part 1 does not capture requirements for sterilizers.

In the Performance requirements section, a WD conforming to the ISO 15883 standards shall have a process which includes, a cleaning stage, disinfection stage, rinsing stage and when appropriate a drying stage.

Annex A describes the test programme for the WD which includes the cleaning efficacy, thermometric control, fluid emission, doors and interlocks, process residuals, chemical dosing, air quality, pipework, ...

ISO 15883-4 - Requirements and tests for Washer-Disinfectors employing chemical disinfection for thermolabile endoscopes.

Part 4 specifies the requirements, including performance, for WDs that are intended to be used for cleaning and chemical disinfection of thermolabile flexible endoscopes. It also specifies the performance requirements for the cleaning and disinfection of the WD and its components and accessories as well as the methods, instrumentation and instructions required for type testing, works testing, validation (installation, operational and performance qualification on first installation), routine control and monitoring and re-validation, periodically and after essential repairs.

Annex C describes a summary of test programs the WD should fulfill to, in addition to those described in Part 1.

ISO/TS 15883-5 - Test soils and methods for demonstrating cleaning efficacy.

Part 5, the Technical Specification (TS), specifies the test soils and methods which can be used to demonstrate the cleaning efficacy of the WD. The difference in test soils does not indicate that they are of equivalent sensitivity in their determination of the cleaning efficacy. Each test soil has its own acceptance criteria which are based upon visual inspection and/or a microbiological end result. In case of chemical detection or residual soiling level is required, additional methods can be complemented.

* ISO 15883 references used:

ISO 15883-1:2006 - General requirements, terms and definitions and tests.
ISO 15883-4:2008 - Requirements and tests for Washer-Disinfectors employing chemical disinfection for thermo-labile endoscopes.
ISO/TS 15883-5:2006 - Test soils and methods for demonstrating cleaning efficacy of Washer-Disinfectors.

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Load types for flexibles endoscopes are described in ISO 15883-5:2006 - Table 1, Summary of test soils including their allocation to the type of load.

| Country code | Annex in Part 5 | Constituents of soils |
|--------------|-----------------|---|
| AT | Annex E | Nigrosin, wheat flour, hens egg, <i>E. faecium</i> |
| DE | Annex I | Blood, <i>E. faecium</i> |
| | Annex J | Tetramethylbenzidine, hydrogen peroxide solution, bovine haemoglobin |
| FR | Annex F | Biofilm formed by <i>Pseudomonas aeruginosa</i> |
| NL | Annex K | Bovine serum albumin, porcine mucin, bovine thrombin, bovine fibrinogen |
| UK | Annex R | Glycerol, dehydrated hog mucin, horse serum, unbleached plain flour, aqueous safranin solution, water |

ISO 15883 Efficacy Test Reports.

All our tests have been validated by an independent laboratory, BIOTECH-GERMANDE, France. The following reports are available:

- Cleaning efficacy of the ADAPTACLEAN™ detergent in the ADAPTASCOPE™ System
- Post washing rinsing
- In-vitro disinfectant efficacy for CIDEX® OPA-C and ADAPTACIDE™ PAA-C
- Disinfection efficacy for CIDEX® OPA-C and ADAPTACIDE™ PAA-C in the ADAPTASCOPE™ System
- Overall cycle efficacy for ADAPTACLEAN™ + CIDEX® OPA-C and ADAPTACLEAN™ + ADAPTACIDE™ PAA-C in the ADAPTASCOPE™ System
- Thermal & chemical disinfection of the liquid transportation system - D1 and D2
- Disinfection of the water treatment equipment
- Final rinse water quality
- Venting and drainage systems

In case you need more details on these reports, please contact your local ASP representative.

ADVANCED STERILIZATION PRODUCTS

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