

ISO 15883-2:2024-11 (E)

Washer-disinfectors - Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for critical and semi-critical medical devices

Contents		Page
Foreword		iv
Introduction		v
1	Scope	1
2	Normative references	1
3	Terms and definitions	1
4	Performance requirements	3
4.1	General	3
4.2	Cleaning	4
4.3	Disinfecting	4
4.4	Temperature of inner surfaces of processed devices	5
4.5	Water quality	5
5	Mechanical and control requirements	5
5.1	Lumen and powered devices	5
5.1.1	Irrigation	5
5.1.2	Verification of flow through lumen and powered devices	6
5.2	Control systems	6
5.3	Process verification	6
6	Testing for conformity	6
6.1	General	6
6.2	Tests for soil removal from chamber walls, load carrier(s) and load	7
6.3	Thermometric tests	7
6.3.1	General	7
6.3.2	Temperature of outer surfaces of devices	7
6.3.3	Temperature of inner surfaces of devices	8
6.4	Pressure and flow measurement	9
7	Information to be provided for the WD	9
8	Information to be requested from the purchaser by the supplier of the WD	9
Annex A (informative)	Summary of test programmes	10
Annex B (informative)	Guidance on the designation of a medical device to a product family for cleaning and thermal disinfection processes	11
Bibliography		14