

DIN EN ISO 15883-5:2021-11 (E)

Washer-disinfectors - Part 5: Performance requirements and test method criteria for demonstrating cleaning efficacy (ISO 15883-5: 2021)

Contents

	Page
European foreword	3
Foreword	4
Introduction	6
1 Scope	7
2 Normative references	7
3 Terms and definitions	7
4 Performance requirements	9
4.1 General	9
4.2 Test soil considerations	9
4.3 Load considerations	10
4.4 Cleaning efficacy test criteria	11
4.4.1 General	11
4.4.2 Visual examination	11
4.4.3 Assay criteria	11
4.4.4 Process residuals	13
5 Testing for conformity	13
5.1 Cleaning test method validation	13
5.1.1 General	13
5.1.2 Load soiling method	13
5.1.3 Detection method(s)	13
5.1.4 Analyte assay method	14
5.2 Washer-disinfector requirements	14
5.3 Cleaning type test	14
5.3.1 Principle	14
5.3.2 Reagents/materials	14
5.3.3 Procedure	14
5.3.4 Acceptance criteria	14
5.4 Cleaning performance qualification test	15
5.4.1 Principle	15
5.4.2 Reagents/materials	15
5.4.3 Procedure	15
5.4.4 Acceptance criteria	15
5.5 Process residuals	15
5.5.1 General	15
5.5.2 Risk analysis	16
5.5.3 Cytotoxicity	16
5.5.4 Sampling methods	16
5.5.5 Acceptance criteria	16
Annex A (informative) Examples of test soils	17
Annex B (normative) Protein-based test soil performance assessment	22
Annex C (informative) Examples of test methods for the detection and assessment of residual proteinaceous contamination	44
Annex D (informative) Examples of test methods for the detection of haemoglobin for the assessment of cleaning efficacy	49
Annex E (informative) Test soil performance assessment - Sample results sheets	53
Bibliography	60