

# 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)

---

<b>Contents</b>		<b>Page</b>
<b>European foreword</b> .....		<b>3</b>
<b>Foreword</b> .....		<b>4</b>
<b>Introduction</b> .....		<b>6</b>
<b>1</b>	<b>Scope</b> .....	<b>7</b>
<b>2</b>	<b>Normative references</b> .....	<b>7</b>
<b>3</b>	<b>Terms and definitions</b> .....	<b>7</b>
<b>4</b>	<b>Performance requirements</b> .....	<b>9</b>
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
<b>5</b>	<b>Testing for conformity</b> .....	<b>13</b>
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
<b>Annex A (informative) Examples of test soils</b> .....		<b>17</b>
<b>Annex B (normative) Protein-based test soil performance assessment</b> .....		<b>22</b>
<b>Annex C (informative) Examples of test methods for the detection and assessment of residual proteinaceous contamination</b> .....		<b>44</b>
<b>Annex D (informative) Examples of test methods for the detection of haemoglobin for the assessment of cleaning efficacy</b> .....		<b>49</b>
<b>Annex E (informative) Test soil performance assessment – Sample results sheets</b> .....		<b>53</b>
<b>Bibliography</b> .....		<b>60</b>