



















**CHANGES OF THE NORM DIN EN ISO 15883 PART 4 FLEXIBLE ENDOSCOPES  
IN EFFECT WITH JUNE 2020**

**spypach endoscopic surrogate device fulfills 100 %  
all prescribed test and measurement specifications of the latest DIN EN ISO 15883-part 4  
incl. annex „H“ endoscopic type test group and blocks. (spypach patent: PCT 2051745)  
(Optional with original endoscopic tubes, adapters and lots of measure and test equipment)**

*(text translated from German version)*

4. Performance requirements	Norm met with spypach dummy	Product pictures
<p><b>4.1.2 Equipment</b> All equipment, including all device channels, must be handled by the washer disinfector machine (WD) (a) leak test, b) cleaning, c) disinfection, d) final rinsing, e) rinsing, f) drying)</p>		
<p><b>4.1.4 Operating instructions WD</b> A leak test must be recommended in the instructions for use of the WD</p>		
<p><b>4.2 Systems for leak testing</b> NOTE: This test is intended to demonstrate that the endoscope during the WD operating cycle will not be damaged by liquid penetration. It is only considered as an endoscope integrity check if all parameters of the WD - Leak test (e.g. pressure, duration, maximum permissible leakage, maximum permissible overpressure) are in line with all essential parameters of the endoscope.</p>		
<p><b>4.3 CLEANING</b> All surfaces (inner and outer!) of the endoscope must be cleaned!</p>		
<p><b>4.4.4 Process monitoring (data logger)</b> The process control of the automatic control system must provide proof of proper cleaning and disinfection results with adherence to pressure and temperature. <b>NOTE:</b> <b>5.4.2 Cleaning temperature control</b> <b>5.4.3 Disinfection temperature control</b> <b>6.2.2 Pressure measurement</b> <b>6.5 leak test</b></p>		



5.2 Channel flushing system of the device	Norm met with spypach dummy	Product pictures
<p><b>5.2.2.2</b> If one or more channels of the device are not connected to the WD, the automatic control must trigger an error message.</p> <p><b>NOTE:</b> 6.6 Check that channels are not blocked 6.7 Checking for channels that are not connected</p>		
<p><b>6. Compliance check</b></p>		
<p><b>6.6.3 Implementation</b> For each endoscope type test group defined in Appendix "H", the test <u>must be carried out with a surrogate</u>. (Appendix "H" with block A or B and "Y" connectors)</p> <p><b>6.7.2 Test material</b> The test must be carried out with a surrogate (test dummy device) (see also Appendix B.2.2 test specimen)</p> <p><b>NOTE 6.6.3:</b> <b>National supervisory authorities can require these tests!</b></p> <p><b>6.11.4. Execution</b> Tests with real endoscopes may only be carried out <u>after</u> the tests on the surrogate (endoscope dummy) have been successfully completed</p>		 <p>All models of an endoscope can be produced by spypach!</p>
<p><b>ANNEX A.3 Installation and operation of a WD</b></p> <p>Once the WD is installed on site, the overall responsibility for ensuring that the WD is correctly installed and functioning properly rests solely by the buyer, operator, user (i.e. doctor, hospital) which includes:</p> <ul style="list-style-type: none"> <li>• Installation qualification</li> <li>• Functional qualification</li> <li>• Performance qualification</li> <li>• Requalification</li> <li>• Regular routine tests</li> <li>• The use of the recommended process chemicals</li> </ul>		 <p><b>Spypach endoscopic competence center supports you in all your responsibilities</b></p>