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<b>Work Instruction (Inspection)</b>		<b>Document No.:</b> <b>WI-R-EMEA-CERT-INSP-PCS021</b>
<b>EMEA CERTIFICATION SCHEMES - PRODUCT CONTROL SPECIFICATIONS</b>		
Issue Date: 11 <sup>th</sup> Feb 2015	Revision Date: 08 <sup>th</sup> March 2019	Approved by: Fredrik Wennersten
	Effective Date: 08 <sup>th</sup> April 2019	

### 1.0 Purpose

Product Control Specifications (PCS) specify the requirements for routine inspections, tests, Product Verification Tests and sample selection for products certified under an Intertek EU Type 5 certification scheme (including GS, S, BEAB, ASTA, ENEC, BAUART and TICK MARK). They are for use by manufacturers and by factory inspectors.

### 2.0 Scope

Products: MEDICAL ELECTRICAL EQUIPMENT  
Standards: EN 60601-1  
Marks: S, BEAB

### 3.0 Routine inspections and tests

#### 3.1 General

The following requirements apply to most products.

Variations may be permitted by a prior written agreement from the certification body.

The factory should have a quality plan defining all inspections and tests on materials, components and completed products as appropriate.

Completed products shall be marked to confirm satisfactory completion of all required testing.

Any products which fail inspection or testing shall be segregated and not allowed to continue through the process until rectified and re-inspected or retested.

Products shall not be released until the testing equipment has been checked again following a production batch.

Records of inspections and test should be maintained and held for at least two years.

Records shall include:

- Type of product
- Date of test
- Place of manufacture
- Quantity tested
- Number of failures and actions taken

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### 3.2 Required inspections and tests

Inspection/test	Test parameters	Sampling plan												
<p><b>Measurement of leakage current:</b></p> <p>Earth Leakage Current in plug-connected Class I equipment with accessible earthed parts. (This is Touch Current with open earth lead.)</p> <p>Earth Leakage Current in Permanently Installed Class I equipment.</p> <p>Irrespective of Class, if an applied part is present, the Patient Leakage Current shall not exceed the limits in the table.</p> <p>If values significantly higher than the typical value are measured, the reason to the discrepancy should be investigated and evaluated, even if the values are below the standard limits.</p>	<p>Max. allowed is 0.5 mA. (See fig. 12 and 13 in EN 60601-1)</p> <p>Max. allowed is 5 mA.</p> <p style="text-align: center;">Limits for Patient Leakage Current</p> <table border="1" style="margin-left: auto; margin-right: auto;"> <thead> <tr> <th>Degree of protection</th> <th>B/BF</th> <th>B/BF</th> <th>CF</th> </tr> </thead> <tbody> <tr> <td>NC</td> <td>0.1 mA AC</td> <td>0.01 mA DC</td> <td>0.01 mA AC/DC</td> </tr> <tr> <td>SFC</td> <td>0.5 mA DC</td> <td>0.05 mA DC</td> <td>0.05 mA AC/DC</td> </tr> </tbody> </table> <p>(See fig. 15 in EN 60601-1)</p> <p>NC = Normal Condition SFC = Single Fault Condition (open earth lead)</p>	Degree of protection	B/BF	B/BF	CF	NC	0.1 mA AC	0.01 mA DC	0.01 mA AC/DC	SFC	0.5 mA DC	0.05 mA DC	0.05 mA AC/DC	100%
Degree of protection	B/BF	B/BF	CF											
NC	0.1 mA AC	0.01 mA DC	0.01 mA AC/DC											
SFC	0.5 mA DC	0.05 mA DC	0.05 mA AC/DC											
<p><b>Protective Earth impedance test:</b></p> <p>For Class I equipment a current of at least 10 A, derived from an a.c. source having a no-load voltage not exceeding 12 V, is passed between the Protective Earth terminal and each accessible metal parts, which have to be earthed for safety reasons.</p>	<p>For permanently installed equipment and equipment with an appliance inlet the impedance shall not exceed 0.1 ohm.</p> <p>For equipment with a non-detachable power supply cord the impedance shall not exceed 0.2 ohm when measured from the earth contact in the mains plug.</p>	100%												

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If values significantly higher than the typical value are measured, the reason to the discrepancy should be investigated and evaluated, even if the values are below the standard limits.		
<b>Dielectric strength test according to table and note below:</b>	Duration 2 – 5 seconds	100%

Application of test voltage	Test voltage	
	Class II appliances	Class I appliances
Over 1 MOP (basic insulation) (mains – protectively earthed parts)	--	1 MOOP 1 MOPP 1,500 V a.c. rms
Over 2 MOP (double or reinforced insulation) (mains – accessible non-earthed metal parts) <sup>1)</sup>	2 MOOP 3,000 V a.c. rms <sup>1)</sup>	2 MOOP 3,000 V a.c. rms <sup>1)</sup>
	2 MOPP 4,000 V a.c. rms <sup>1)</sup>	2 MOPP 4,000 V a.c. rms <sup>1)</sup>

<sup>1)</sup> Note: All mains transformers shall be tested between primary and secondary with 4.000 V a.c. rms. It is recommended to do this test before the transformer is mounted in the equipment because dielectric test on the complete equipment may be destructive. A certificate of conducted test, issued by the transformer manufacturer, will be sufficient.

<b>Correct Operation Test:</b>	The correct operation is checked for example, by electrical measurements, by verifying functional controls, by verifying the direction of movements and by verifying performance and accuracy.	100%
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#### 4.0 Product Verification Tests/Periodic testing (refer to CIG 021 clause 5.8)

Product verification tests are in addition to the production line inspection and routine tests and are performed on samples taken randomly from the production line. The manufacturer is responsible for conducting or arranging for the following periodic testing to be completed. Records shall be available for review during factory inspection visits.

Certification Mark	Frequency	PVT/periodic testing required
S	(Annual)	PVT is not mandatory but it is recommended to demonstrate ongoing compliance with EU Directives. The three following PVT steps for BEAB is recommended: - See below.
BEAB	Annual	5.7: Humidity treatment (only devices of IPX1 and higher) followed by dielectric strength test according to cl. 8.8. 5.9 & 8.4.2: Enclosures, protective covers and accessible parts. 7.1, 7.2 & 7.3: Markings and its durability and legibility. 8.7.4.6: Touch Current with metal foil on plastic covers (see fig. 14 in EN 60601-1). The limits are 0.1 mA in NC and 0.5 mA in SFC (open protective earth). 8.7.4.7: Patient Leakage Current with mains voltage on Applied Part (see fig. 16 in EN 60601-1). The limits are 5 mA for BF and 0.05 mA for CF. 8.7.4.8: Patient Auxiliary Current during NC. The limits are as in Table 1 under 2 above (see fig. 19 in EN 60601-1). 8.1b) & 13: Abnormal operation (check operation of protective devices, if any). 8.9: Creepage distances and air clearances. 9.8: Mechanical strength. 11.1: Temperatures.
BEAB	Annual	Extended verification that used components are identical with the types listed in the test report e.g. flexible cords, switches, EMC filters, fuses, opto-couplers, power supply units, cooling fans, DC/DC converters, batteries etc.
BEAB	Annual	Additional tests for equipment covered by EN 60601-2-XX and EN 80601-2-XX. To be decided by Intertek in conjunction with certification.

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In cases where the manufacturer does not have the resources to perform the Product Verification Tests, partly or in whole, Intertek is of course happy to assist.

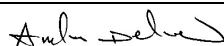
If you have any questions or need assistance, please contact Intertek or simply send us necessary samples with a request for any or all of the above mentioned Product Verification Tests.

### 5.0 Surveillance testing by the Certification Body

If required, samples are selected during the factory inspection and the manufacturer should send these to the address provided. If samples are required but not available at the time of the inspection, the manufacturer should send these as soon as they become available. If there is no stock or production, the manufacturer should advise the certification body that samples will not be provided due to no production.

The certification body will arrange for the required testing to be completed. This will be charged to the manufacturer or Licence holder. A report of the testing will be provided.

<b>Certification Mark</b>	<b>Surveillance testing requirements</b>
S	Regular selection of samples is not required. Samples may be required if any deviations to the type tested or non-compliance with the product standard are suspected.
BEAB	Surveillance samples are selected at the request of the BEAB Surveillance Coordinator.

<b>Document History</b>				
<b>Revision No.</b>	<b>Date</b>	<b>Changes</b>	<b>Name &amp; Title</b>	
			<b>Author</b>	<b>Approving Official</b>
1	11/02/2015	Original issue	Paul Klemets/ R W Hayward	
2	04/09/2017	Earth impedance test current changed in 3.2 and corrections in 4.0 PVT tests	Christoffer Johansson/ Paul Klemets	Fredrik Wennersten

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3	08/03/2019	Earth Leakage Current of 0.5 mA clarified in 3.2.	Peter Lymeus	Fredrik Wennersten

End of Document

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