

**QUALITY INVESTIGATION REPORT**

<b>Q.I.R. No.</b> 002	<b>Customer/Supplier/Dept.:</b> Medical Physics Dept, Nottingham City Hospital	<b>Delivery Note No.:</b> DEL16532 <b>Invoice No:</b> INO78925	<b>Date:</b> 23/01/04
<b>Product Description:</b> Infant Resuscitation Cabinet. Component under investigation is the APGAR Timer.		<b>Product Code:</b> 0310002 (finished cabinet) <b>Supplier Ref:</b> 5550 (for timer)	<b>Batch / Serial No's:</b>
<b>Investigation Required:</b> Peter Smith, Quality Manager at Nottingham City Hospital is refusing to accept the APGAR timer into the Trust as he claims it does not meet the requirements based on the following grounds: <ol style="list-style-type: none"><li>1) The label 'APGAR Timer' designates it as a medical device and as such should be CE marked to the Medical Devices Directive, he claims it is not correctly marked as there is no notified body number.</li><li>2) The timer has been modified and he doubts that it has been properly tested, particularly for EMC, needs to see a Certificate of Conformance for this product before accepting it.</li></ol>			
<b>Signed:</b>	<b>Position:</b> Area Sales Manager	<b>Date:</b> 23/01/04	
<b>Investigation Progress:</b>			
<b>Signed:</b>	<b>Position:</b>	<b>Date:</b>	
<b>Actions Required:</b>			
<b>Signed:</b>	<b>Position:</b>	<b>Date:</b>	
<b>Actions Complete:</b>			
<b>Comments:</b>			
<b>Signed:</b>	<b>Position:</b>	<b>Date:</b>	
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