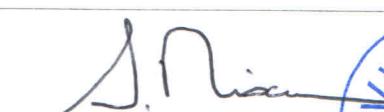


Design Changes QC28 B

Product: Tom Thumb Infant Resuscitators: 0310030 & 0310094	Y/N
Personnel involved: S. Nixon, P. Crossley, S. Hardaker, D.Lamb	
Reason for Change Consolidate the two mounting screws, so that the same dimension part (M6 screw) is used with both the standard Medirail mounted TT480 (0310030) and the pole clamp used with the TT480-PC (0310094)	
Proposed design change & action to be taken Increase the bore of the two spacer/mounting screw sockets on the rear of main Tom Thumb body block (0330201), from M5 to M6. Also change the type of hex screw from dome shaped button head to standard hex socket screw M5 x 10mm.	
Change of function & action to be taken None, device, mounting and usage are unchanged.	
Change to performance & action to be taken The mounting is effectively strengthened with the increase in screw thread bore size. Performance is unchanged.	
Change of usability & action to be taken During manufacture and service, the screws can be more easily and effectively affixed by using a standard hex socket, less chance of tool slippage and unintentional wear to the screw head. No change in usability of the product to the user or patient.	
Change in safety features & action to be taken The mounting is effectively strengthened with the increase in screw thread bore size.	
Application of new standards Not applicable.	

Design Changes QC28 B

Does this have an effect on	
Constituent parts	<input checked="" type="checkbox"/>
<p>0330216 existing M5 x10mm screw to be replaced with 0330245 new part M6 x 10mm screw</p> <p>No risk in the change of screw size.</p>	<input checked="" type="checkbox"/>
Product in process	<input checked="" type="checkbox"/>
<p>To be implemented on the next production batch.</p> <p>No risk to product or user.</p>	<input checked="" type="checkbox"/>
Product already delivered	<input checked="" type="checkbox"/>
<p>No risk, as no change is required.</p>	<input checked="" type="checkbox"/>
Inputs of risk management	<input checked="" type="checkbox"/>
<p>No risk as there is no observable change to the product.</p>	<input checked="" type="checkbox"/>
Outputs of risk management	<input checked="" type="checkbox"/>
<p>No increase in risk.</p>	<input checked="" type="checkbox"/>
Product realization	<input checked="" type="checkbox"/>
<p>P. Crosley to source new part and for it to be added to Opera. Production procedures to be updated.</p> <p>Revised body block drawing to be uploaded to the top level of the drawing file.</p>	<input checked="" type="checkbox"/>
Risk Analysis on any design change Refer QC22	<input checked="" type="checkbox"/>
<p>No change to risk assessment, risk analysis report, risk management review.</p>	<input checked="" type="checkbox"/>
<p>Signed:</p> <p>Steve Nixon Director – Viamed Ltd.</p>	  <p>Viamed Company registered in England Company Registration Number 0123456789</p>