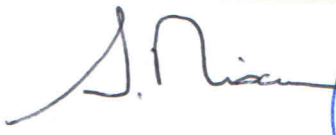



## Design Changes    QC28 B

<b>Product:</b> Tom Thumb Infant Resuscitators: 0310030 & 0310094	Y/N
<b>Personnel involved:</b> S. Nixon, P. Crossley, S. Hardaker, D.Lamb	
<b>Reason for Change</b>  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)	
<b>Proposed design change &amp; action to be taken</b>  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.	
<b>Change of function &amp; action to be taken</b>  None, device, mounting and usage are unchanged.	
<b>Change to performance &amp; action to be taken</b>  The mounting is effectively strengthened with the increase in screw thread bore size. Performance is unchanged.	
<b>Change of usability &amp; action to be taken</b>  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.	
<b>Change in safety features &amp; action to be taken</b>  The mounting is effectively strengthened with the increase in screw thread bore size.	
<b>Application of new standards</b>  Not applicable.	

## Design Changes    QC28 B

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