

QC 21 Non Conformance Report

Date	22.10.2020
Issue id unique identifier	201667
BSI Ref (if applicable) unique identifier	1970716-202010-N1
Responsibility Person Overall responsible	Derek Lamb
Non-Conformance statement of the problem	The statement of the problem: The Non-applicable and exclusion clauses were not clearly defined.
Investigation By: Person responsible	Derek Lamb / Helen Lamb
Investigation Issue id (if applicable) Root Cause Analysis	201673 Root Cause Analysis When we reduced our scope, from manufacturing CE products under the MDD, to just supplying other manufactures finished CE products. We were not clear enough in which sections were Excluded from scope, and which sections had 'parts' that were Not Applicable.
Corrective Action By: Person responsible	Derek Lamb
Corrective Action Issue ID (if applicable): Relevant and Proportionate Corrective Action	#200653
Time Scale for Corrective Action Time for completion of all identified actions	Immediate Action and Corrective Action to be carried out by 22 nd November 2020
Corrective Action:	Immediate Action Review these sections in the route map labelled as Excluded. Correct those that are labelled incorrectly.

	Make sure that those section that are Not Applicable should be labelled as such. Corrective Action Review the route map the make sure there are no other miss labelled sections. Add notes to the section indicated as Not Applicable or Excluded, to state why they are described as such. In the recurring issue to review the Route Map add a specific statement to review these section that are labelled as Not Applicable or Excluded.
Follow-up future issue id (Effectiveness verification)	
Effectiveness verification	ISO Visit where the route map is checked and verified in detail by the BSI Auditor.
Closed By:	
Closed on	