

Minor (3) nonconformities arising from this assessment.

Finding Reference	1970716-202010-N1	Certificate Reference	MD 78787
Certificate Standard	ISO 13485:2016 & EN ISO 13485	Clause	4.2.2
Category	Minor		
Area/process:	Scope/product changes, manual, policy, Management review, objectives, targets, data analysis		
Statement of non-conformance:	The Non-applicable and exclusion clauses were not clearly defined.		
Clause requirements	<p>Quality manual</p> <p>The organization shall document a quality manual that includes:</p> <ul style="list-style-type: none"> a) the scope of the quality management system, including details of and justification for any exclusion or non-application; b) the documented procedures for the quality management system, or reference to them; c) a description of the interaction between the processes of the quality management system. <p>The quality manual shall outline the structure of the documentation used in the quality management system.</p>		
Objective Evidence	Quality Manual vers 45498 of 12 October 2020		
Cause			
Correction/containment			
Corrective action			