If there is discrepancy, an action is needed to improve the PROCESS.

The list can also be used for an EVALUATION of the PROCESSES after the action has been performed.

Table D.1 – Checklist for small companies without a certified QMS

ACTIVITY	Related clause of ISO 13485:2003	Covered by existing procedure?	If yes: Reference	Actions to be taken
5.1 Software development planning	7.3.1 Design and development planning	Yes/No		
5.2 Software requirements analysis	7.3.2 Design and development inputs	Yes/No		
5.3 Software ARCHITECTURAL design		Yes/No		
5.4 Software detailed design		Yes/No		
5.5 SOFTWARE UNIT implementation and verification		Yes/No		
5.6 Software integration and integration testing		Yes/No		
5.7 SOFTWARE SYSTEM testing	7.3.3 Design and development outputs 7.3.4 Design and development review	Yes/No		
5.8 Software release	7.3.5 Design and development verification 7.3.6 Design and development validation	Yes/No		
6.1 Establish software maintenance plan	7.3.7 Control of design and development changes	Yes/No		
6.2 Problem and modification analysis		Yes/No		
6.3 Modification implementation	7.3.5 Design and development verification 7.3.6 Design and development validation	Yes/No		
7.1 Analysis of software contributing to hazardous situations		Yes/No		
7.2 RISK CONTROL measures		Yes/No		
7.3 VERIFICATION of RISK CONTROL measures		Yes/No		
7.4 RISK MANAGEMENT of software changes		Yes/No		
8.1 Configuration identification	7.5.3 Identification and traceability	Yes/No		
8.2 Change control	7.5.3 Identification and traceability	Yes/No		
8.3 Configuration status accounting		Yes/No		
9 Software problem resolution PROCESS		Yes/No		