Table 1 Summary of information in Quality Manual

	SUBJECT	ISO 13485 REFERENCES
1	Cover page, table of contents	==========
2	Company profile (refer below)	==========
3	Control and distribution	==========
4	Quality Management System	4.0
	General requirements	4.1
	Documentation requirements	4.2
5	Management Responsibility	5.0
	Management commitment	5.1
	Customer focus	5.2
	Quality Policy	5.3
	Planning	5.4
	Responsibility, authority and communication	5.5
	Management review	5.6
6	Resource Management	6.0
	Provision of resources	6.1
	Human resources	6.2
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	Work environment and contamination control	6.4
7	Product Realization	7.0
	Planning of product realization	7.1
	Customer Related Processes	7.2
	Design and development	7.3
	Purchasing	7.4
	Production and service provision	7.5
	Control of monitoring and measuring equipment	7.6
8	Measurement, Analysis and Improvement	8.0
	General	8.1
	Monitoring and measurement	8.2
	Control of Nonconforming Product	8.3
	Analysis of data	8.4
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	SUBJECT	ISO 13485 REFERENCES
9	**List of procedures**	==========
10	**Glossary of terms**	==========
11	**Process flow chart**	==========
12	**Quality Policy**	==========
13	**Organization structure**	==========

4 REFERENCE

ISO 13485:2016 Medical devices – Quality management systems – Requirements for regulatory purposes

5 UPDATE HISTORY

Date	Reason for update	Version & Publication
February 2017	First publication for comment	Version 1, March 2017
28 April 2017	Due date for comment	
June 2017	Changes to sections 1, 2, 3.2, 3.3 and Table 1	Version 2, Aug 2017
With immediate effect	Implementation	
November 2019	Administrative update: Medicine Control Council to South African Health Products Regulatory Authority MCC to SAHPRA Registrar of Medicine to Chief Executive Officer	Version 2, November 2019