

<i>Company logo</i> <i>Company name</i>	SUMMARY TECHNICAL DOCUMENTATION	Page 1 of 18
	SP-MMS-004	Revision #: 0 Date (mm/dd/yyyy):

DOCUMENT CONTROL	
Superseded document:	
Effective date (mm/dd/yyyy):	

DOCUMENT APPROVAL			
	Name and Title	Signature	Date (mm/dd/yyyy)
Author			
Reviewer			
Approver			

<i>Company logo</i> <i>Company name</i>	SUMMARY TECHNICAL DOCUMENTATION	Page 2 of 18
	SP-MMS-004	Revision #: 0 Date (mm/dd/yyyy):

Table of Contents

1PURPOSE.....	3
2SCOPE.....	3
3TERMS AND DEFINITIONS.....	3
4RESPONSIBILITY AND AUTHORITY.....	7
4.1REGULATORY AFFAIRS DEPARTMENT.....	7
5DESCRIPTION OF ACTIVITIES.....	7
5.1IVD TECHNICAL REPORT FORMAT.....	7
5.2TABLE OF CONTENTS.....	8
5.3DEVICE DESCRIPTION AND PRODUCT SPECIFICATION.....	9
5.3.1DEVICE DESCRIPTION.....	9
5.3.2PRODUCT SPECIFICATION.....	10
5.3.3REFERENCE TO PREVIOUS GENERATION(S) OR SIMILAR DEVICES.....	10
5.4Essential Requirements CHECKLIST.....	10
5.5RISK ANALYSIS AND CONTROL SUMMARY.....	11
5.6PRODUCT VERIFICATION AND VALIDATION.....	11
5.6.1STERILIZATION.....	13
5.6.2BIOCOMPATIBILITY.....	14
5.6.3COMBINATION DEVICES.....	14
5.6.4SOFTWARE VERIFICATION AND VALIDATION.....	14
5.6.5BIOLOGICAL SAFETY.....	14
5.6.6ANIMAL STUDIES.....	15
5.6.7MEDICINAL SUBSTANCES.....	15
5.6.8CLINICAL EVIDENCE.....	15
5.7DESIGN AND MANUFACTURING INFORMATION.....	16
5.7.1MANUFACTURING PROCESSES.....	16
5.7.2DESIGN AND MANUFACTURING SITES.....	16
5.8LABELING.....	16
6REFERENCES.....	17
7FORMS.....	17
8ATTACHMENTS.....	17
9DOCUMENT CHANGES.....	17
9.1DOCUMENT CHANGES IDENTIFICATION.....	17
9.2REASON FOR CHANGES.....	18

<i>Company logo</i> <i>Company name</i>	SUMMARY TECHNICAL DOCUMENTATION	Page 18 of 18
	SP-MMS-004	Revision #: 0 Date (mm/dd/yyyy):

Revision #	Description of Change	DCR #	Effective Date (dd/mm/yyyy)

9.2 REASON FOR CHANGES