



<b>Doc Number:</b> GLF-MD-14A  Revision: 1.0	<b>CLASSIFICATION MATRIX/</b>	 Effective date: 15 May 2024
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**CLASSIFICATION MATRIX**


**Legend:**

R=Required; NR; Not required; CR= Conditionally required; O=Optional; OR=Optional but recommended


CODE: Chapter Level	Display Name	cl a s s i f i c a t i o n	CLASS: New  Condition
<b>CHAPTER 1 – REGIONAL ADMINISTRATIVE</b>			
1.01	Cover Letter	R	
1.02	Submission Table of Contents	R	
1.03	List of Terms/Acronyms	R	
1.04	Application Form/Administrative Information	R	
1.05	Listing of Device(s)	R	
1.06	Quality Management System, Full Quality System or other Regulatory Certificates	R	
1.07	Free Sale Certificate/ Certificate of Marketing authorization	CR	
1.08	User Fees	R	

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<b>1.09</b>	Pre-Submission Correspondence and Previous Regulator Interactions	<b>CR</b>	
<b>1.11</b>	Acceptance for Review Checklist	R	
<b>1.12</b>	Statements/Certifications/Declarations of Conformity	R	
<b>1.13</b>	Letters of Reference for Master Files	R	
<b>1.14</b>	Letter of Authorization	R	
<b>1.15</b>	Other Regional Administrative Information	R	
<b>CHAPTER 2 – SUBMISSION CONTEXT</b>			
<b>2.01</b>	Chapter Table of Contents	R	
<b>2.02</b>	General Summary of Submission	R	
<b>2.03</b>	Summary and Certifications for Premarket Submissions	R	
<b>2.04</b>	Device Description	R	
<b>2.05</b>	Indications for Use and/or Intended Use	R	
<b>2.06</b>	Global Market History	R	
<b>2.07</b>	Other Submission Context Information	R	
<b>CHAPTER 3 – ANALYTICAL PERFORMANCE AND OTHER EVIDENCE</b>			
<b>3.01</b>	Chapter Table of Contents	R	
<b>3.02</b>	Risk Management	R	
<b>3.03</b>	Essential Principles (EP) Checklist	R	
<b>3.04</b>	Standards	R	
<b>3.05</b>	Analytical Performance	R	
<b>3.06</b>	Other Studies	R	
<b>3.07</b>	Analytical Performance and Other Evidence Bibliography	R	
<b>3.08</b>	Other Evidence	R	

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<b>CHAPTER 4 – CLINICAL EVIDENCE</b>		
<b>4.01</b>	Chapter Table of Contents	R
<b>4.02</b>	Overall Clinical Evidence Summary	R
<b>4.03</b>	IRB Approved Informed Consent Forms	R
<b>4.04</b>	Investigators Sites and IRB contact information	R
<b>4.05</b>	Other Clinical Evidence	R
<b>CHAPTER 5 – LABELLING AND PROMOTIONAL MATERIAL</b>		
<b>5.01</b>	Chapter Table of Contents	R
<b>5.02</b>	Product/Package Labels	R
<b>5.03</b>	Package Insert/Instructions for Use	R
<b>5.04</b>	e-labelling	OR
<b>5.05</b>	Patient Labelling	R
<b>5.06</b>	Technical/Operators Manual	R
<b>5.07</b>	Product Brochures	R
<b>5.08</b>	Other Labelling and Promotional Material	R
<b>CHAPTER 6A – QUALITY MANAGEMENT SYSTEM PROCEDURES</b>		
<b>6A.01</b>	Cover Letter	R
<b>6A.02</b>	Chapter Table of Contents	R
<b>6A.03</b>	Administrative	R
<b>6A.04</b>	Quality management system procedures	R
<b>6A.05</b>	Management responsibilities procedures	R
<b>6A.06</b>	Resource management procedures	R
<b>6A.07</b>	Product realization procedures	R

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<b>6A.08</b>	Design and development procedures	R	
<b>6A.09</b>	Purchasing procedures	OR	
<b>6A.10</b>	Production and service controls procedures	R	
<b>6A.11</b>	Control of monitoring and measuring devices procedures	R	
<b>6A.12</b>	QMS measurement, analysis and improvement procedures	R	
<b>6A.13</b>	Other Quality System Procedures Information	R	
<b>CHAPTER 6B – QUALITY MANAGEMENT SYSTEM DEVICE SPECIFIC INFORMATION</b>			
<b>6B.01</b>	Chapter Table of Contents	R	
<b>6B.02</b>	Quality management system information	R	
<b>6B.03</b>	Management responsibilities information	R	
<b>6B.04</b>	Resource management information	OR	
<b>6B.05</b>	Device Specific Quality Plan	R	
<b>6B.06</b>	Product realization information	R	
<b>6B.07</b>	Design and development information	R	
<b>6B.08</b>	Purchasing information	OR	
<b>6B.09</b>	Production and service controls information	R	
<b>6B.10</b>	Control of monitoring and measuring devices information	R	
<b>6B.11</b>	QMS measurement, analysis and improvement information	R	
<b>6B.12</b>	Other Device Specific Quality Management System Information	R	