Appendix III

Technical documentation details according to the classification

	General IVD	Self-testing	List A	List B
1- Administration	**Applied for all classes**			
• Name of manufacturer				
• Address of manufacturer				
• Address of any associated manufacturing sites				
• Statement of legal liability				
• License of manufacturing no. (attachment)				
• Name of authorized person • Authorized person Delegation Letter (attachment)				
• Name of contact person				
• Tel				
• Fax				
• E- mail				
• Web address				
• 13485:2016, and CE certificate according to IVD, or IVDR If present (attachment)				
• Declaration of conformity / letter of declaration according to the adopted regulation (attachment) • N.B: the adopted regulation to be one of the GHTF member				
2-Device description	**Applied for all classes**			
• Name of the device				
• Brand name				
• Codes				
• Intended use				
• Risk classification according to European				

	General IVD	Self-testing	List A	List B
regulation.				
• Description of principle of the assay and methodology used				
• Description of individual components included in the IVD				
• Where applicable, the following should also be provided				
• A description of the accessories, other IVDs and other products that are not medical devices which are intended to be used in combination with the IV				
• For assays requiring instrumentation, a description of the relevant instrumentation characteristics or details of dedicated instrumentation to be used				
• A description of any software to be used				
• A complete list of any configurations or variants of the IVD, other than kit size, that will be made available.				
3-Device history (Transitional State only)	**Applied for all classes**			
4-Risk analysis and control summary	**Summary**	**Summary**	**Summary**	**detailed report**
5-Design information	**Summary**	**description of the design aspects that make it suitable for lay person use**		**detailed information on material specifications would be provided.**

	General IVD	Self-testing	List A	List B
6-manufacturing information	summary	summary	summary	Summary
7-Clinical evidence report (if IVDR applied)				Detailed
8-Clinical summary report (if IVDR applied)				Detailed
9-Performance evaluation Diagnostic sensitivity Diagnostic specificity	Summary	Summary	Detailed	Detailed
10-Product Validation and Verification (Attachment)				
1.Specimen type	Summary	Summary	Summary	Detailed
2.Accuracy	Summary	Summary	Detailed	Detailed
3.Analytical sensitivity	Summary	Summary	Detailed	Detailed
4.Analytical specificity	Summary	Summary	Detailed	Detailed
5.Measuring range of assay	Summary	Summary	Detailed	Detailed
6.Traceability of calibrator and controls	Summary	Summary	Summary	Detailed
7.Determination of assay cut-off	Summary	Summary	Detailed	Detailed
8.Verification and validation of instrumentation/software				
9.Stability study	Summary	Summary	Detailed	Detailed
10.Labeling	Applied for all classes			
11.Manufacturing process and control	Applied for all classes			
12.In process inspection and testing	Applied for all classes			
13. Finished product assembly and testing reports				
14.Product release process and statement of compliance				
15.Manufacturer testing reports				
16.Commitment to follow up with medical device Post-Market Surveillance (PMS).				