Submission Details

Product name:	
Manufacturer:	
Classification of IVDD:	
Date Registration of IVDD:	

TABLE 1			
	Report date	Reviewed by	Date of review
Post market surveillance report #1			
Post market surveillance report #2			
Post market surveillance report #3			
Post market surveillance report #4			

TABLE 2 POST MARKET SURVEILLANCE REPORT	
Date product went on the market	
Number of units sold	
Number of complaints	
Complaint rate	
Have there been any trends identified in relation to complaints	
Number of adverse events	
Number of adverse events rest of world	
Were there any unforeseen risks?	
Number of vigilance reports to Competent Authority	
Vigilance report rate	
Number of worldwide reportable incidents	
Number of product recalls in Tanzania	
Number of product recalls worldwide	

Were there any corrective actions arising from complaints or adverse events	
What is the status of the corrective action	
Who authorized the post market surveillance report	
Did a clinical expert review this post market surveillance	
Please provide bio /CV of author	
Please provide bio/CV of clinical expert	
In the case of CAPA'S or recalls please give details below:	

SECTION 1: DETAILED DESCRIPTION OF COMPLAINTS:					
Detailed description of complaints Tanzania:					
Please indicate in each event if the complaints were due to:					
1.	User error				
2.	Procedure error				
3.	Product malfunction				
4.	Unanticipated events				
5.	Alleged direct harm caused to the patient or user of the device				
Are there any new emerging risks:		Yes	☐	No	☐
Discuss new risks if applicable :					
Has an external clinical expert been engaged to review the new risks?					
Detailed description of complaints:					

Please indicate in each event if the adverse events were due to:				
1. User error 2. Procedure error 3. Product malfunction				
Are there any new emerging risks:	**YES**	☐	**NO**	☐
Discuss new risks if applicable :				
If recalls occurred please discuss				

SECTION 2: VIGILANCE REPORTING		
Has a vigilance report been sent to a Competent Authority:	Yes ☐	No ☐
Has a vigilance report been sent to NSAI:	Yes ☐	No ☐
Please list all vigilance reports with identifier number:		
If yes, discuss each report in detail and provide copies of the reports, if not already submitted to NSAI:		

SECTION 3: RISK MANAGEMENT		
Has the risk management file been updated to reflect these events:	Yes ☐	No ☐
Has the CER been updated to reflect these events:	Yes ☐	No ☐
Does the benefit of the product still outweigh the risk taking account “State of the Art” :	Yes ☐	No ☐

SECTION 4: PERFORMANCE		
Is the device performing as intended, in line with the design of the device?	Yes ☐	No ☐