Device Deficiency

REPORT INFORMATION	
Report type	☐ Initial ☐ Follow-up
Report Date (dd/mm/yyyy)	

CLINICAL STUDY INFORMATION	
Protocol ID	**H-34**
Study unique identification number	**01**

INFORMATION ON THE STUDY SITE	
Name of the healthcare facility	
Name of the Principal Investigator	

MEDICAL DEVICE INFORMATION	
Name of the medical device	
Components	

INFORMATION ON THE CLINICAL STUDY SUBJECT	
ID number of study subject	

DEVICE DEFICIENCY INFORMATION	
Onset date (dd/mm/yyyy)	
Classification of the device deficiency	☐ Malfunction ☐ User Error ☐ Inadequate labelling / IFU ☐ Inadequate Performance
Description of Deficiency and any action taken:	

Could this device deficiency have led to a SERIOUS ADVERSE EVENT if suitable action had not been taken, intervention had not been made, or if circumstances had been less fortunate?	☐ Yes ☐ No

NOTES

Attachments		
If any, please specify	☐	

INFORMATION ON SUBMITTER OF THE REPORT	
Submitter	☐ Principal Investigator ☐ Other (identify the role of the delegated person by the Principal Investigator)_____
Name of submitter Signature of submitter Date of signature	_____ _____ _____