HAEMOVIGILANCE UNIT
HEALTH CARE STANDARDS DIRECTORATE
DEPARTMENT OF PUBLIC HEALTH REGULATION
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Health Care Standards Directorate
Superintendence of Public Health
Ministry for Health

BLOOD SERIOUS ADVERSE EVENT (SAE) REPORT FORM

Report Identification Number (given by reporting establishment) _____

DETAILS OF SERIOUS ADVERSE EVENT

Date of SAE (DD/MM/YYYY):				
Serious Adverse Event (SAE) which may affect the quality and safety of blood component due to a deviation in:	**Specification**			
	Product defect	**Equipment Failure**	**Human error**	**Other (please specify)**
Whole blood collection	☐	☐	☐	☐
Apheresis collection	☐	☐	☐	☐
Testing of donations	☐	☐	☐	☐
Processing	☐	☐	☐	☐
Storage	☐	☐	☐	☐
Distribution	☐	☐	☐	☐
Materials	☐	☐	☐	☐
Other	☐	☐	☐	☐

REPORTING ESTABLISHMENT

Type *(please circle)***:** hospital blood bank, blood establishment, hospital, clinic, manufacturer, bio-medical research institution
Report made by (Name):
Address:
Telephone/Mobile:
E-mail address:

Signature _____ **Date of Report** _____

IDENTIFICATION NUMBER OF REPORTING ESTABLISHMENT: _____
(For office use only)