

Please send completed form to:
 Health Care Services Standards Directorate
 Biovigilance
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 Email: healthstandards.sph@gov.mt
 Url: <https://deputyprimeminister.gov.mt/en/hcs/Pages/hcs.aspx>



Health Care Standards Directorate

Superintendence of Public Health

Ministry for Health

For office use only

Reference Number:

**SERIOUS ADVERSE EVENTS REPORT FORM
 HUMAN TISSUES AND CELLS**

Rapid notification for Suspected Serious Adverse Events

Establishment/Organisation	
Department	
Address	
Tissue establishment	
Report identification (<i>unique identification number given at reporting site</i>)	

Reporting date (dd/mm/yyyy)	
Date and place of serious adverse event (dd/mm/yyyy)	

Type of serious adverse event				
Serious adverse event which may affect quality and safety of tissues and cells due to a deviation in:	Specification			
	Tissues and cells defect	Equipment failure	Human error	Other (specify)
Procurement				
Testing				
Transport				
Processing				
Storage				
Distribution				
Materials				
Others (specify)				

Reporter's Name	
Title	
Signature	
Email address	
Telephone number	

Supply of report forms required Yes No