SOP 03

Annex 05 – Medical Device – Public Incident Report Form

CdG Ref. No.		Date Received	

Product Complaint made by:

☐ Tick the box if you wish to keep the information below confidential

Reported Name and Surname		Profession (if HCP)	
Patient Initials		Age	
Male/Female			
Contact details*			

**Contact details are required by the company to be able to have a point of reference for further information (if required) and to be able to provide feedback to the user/professional reporting the incident.*

Medical Device Details

Medical Device Brand / Generic Name	
Batch Number / Serial Number	
Expiry Date	
Device Obtained From	

Incident Details

Date of Incident	
Description of Incident	
Was device retained?	
Was an injury incurred? If yes, please explain	

Data Protection Consent Statement

The person putting forward the report hereby consents to the processing of personal data by the Charles de Giorgio Ltd. and understands that this data shall be processed in accordance with the General Data Protection Regulation (GDPR), Regulation 2016/679/EU of the European Parliament and of the Council of 27 April 2016, repealing Directive 95/46 EC, the Data Protection Act (Chapter 586 of the Laws of Malta) and the Company Data Protection Policy. The person also understands that Charles de Giorgio Ltd. shall process this personal data in line with the purposes they are collected for in this form.

Signature		**Date**	