Medical Device Incident User Report Form

If you have experienced a problem with a medical device, please complete this form and send it to the Health Products Regulatory Authority, Kevin O’Malley House, Earlsfort Centre, Earlsfort Terrace, Dublin 2, D02 XP77, or contact us by telephone at 01-6764971 or by email at devicesafety@hpra.ie.

**A privacy notice in relation to the personal data collected on this form is available on the HPRA website (**[**www.hpra.ie**](http://www.hpra.ie)**) under the ‘Report an Issue’ tab and by clicking on ‘Medical Device Adverse Incident’.**

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| SECTION 1: Contact Details of Reporting Organisation |
| **Name of organisation:** |       |
| **Address of organisation:** |       |
| **Contact name:** |       |
| **Position:** |       |
| **Telephone number:** |       |
| **Email address:** |       |
| **Fax number:** |       |

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| SECTION 2: Device Details |
| **Name of device and model number:**      |
| **Type of device (e.g. pacemaker):**       |
| **Serial number/batch number/lot number:**       |
| **Where did you get the device?**       |
| **Name of the person who supplied the device:**       |
| **Name and address of the manufacturer:**       |
| **Name and address of the distributor:**      |

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| SECTION 3: Incident Details |
| **What went wrong with the device?**      |
| **On what date did the incident occur?**       |
| **Was an injury suffered? [ ]  Yes [ ]  No** |
| **If an injury was suffered, please provide details:**      |
| **Have you contacted the manufacturer / authorised representative / supplier?** [ ]  Yes [ ]  No |