National Research Ethics Committee for Medical Devices (NREC-MD)

Cover Form for a Safety Report V2

**This cover form should be completed by the Sponsor and should be submitted with any safety reports.**

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| **A. CLINICAL INVESTIGATION IDENTIFICATION** |
| Unique Device Identification (UDI): | Click or tap here to enter text. |
| Title of clinical investigation: | Click or tap here to enter text. |
| NREC Application Number[[1]](#footnote-2): | Click or tap here to enter text. |
| Date of final ethics approval: | Click or tap here to enter text. |
| Study sites (for each site please include names of site lead investigator) | Click or tap here to enter text. |

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| **B. APPLICANT IDENTIFICATION** |
| Principal Investigator name: | Click or tap here to enter text. |
| Title: | Click or tap here to enter text. |
| Position: | Click or tap here to enter text. |
| Institution: | Click or tap here to enter text. |
| Email: | Click or tap here to enter text. |
| Mobile: | Click or tap here to enter text. |
| Sponsor details (or Legal Representative if Sponsor is not established in the European Union): | Click or tap here to enter text. |

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| **C. Complete this section only if your study is a clinical investigation of a medical device that received ethics approval under the Directive 93/42/EEC or 90/385/EEC (SI 252/1994 or SI 253/1994).** |
| Name of REC that approved the study | Click or tap here to enter text. |
| Application ID assigned by local REC | Click or tap here to enter text. |
| Final approval date | Click or tap here to enter text. |
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| **D. LIST OF ENCLOSED DOCUMENTATION** |
| Reporting Period: | Click or tap here to enter text. |
| Date of Report: | Click or tap to enter a date. |

1. If this study received ethics approval under the Directive 93/42/EEC or 90/385/EEC (SI 252/1994 or SI 253/1994) and does not have an NREC Application number, please insert NA. [↑](#footnote-ref-2)