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

Cover Form for a Safety Report

**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: | Click or tap here to enter text. |
| Title of clinical investigation: | Click or tap here to enter text. |
| NREC application number: | Click or tap here to enter text. |
| Name of site(s): | Click or tap here to enter text. |
| Submission date: | Click or tap to enter a date. |

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| B. APPLICANT IDENTIFICATION | |
| 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. LIST OF ENCLOSED DOCUMENTATION | |
| Reporting Period: | Click or tap here to enter text. |
| Date of Report: | Click or tap to enter a date. |