**NATIONAL COMPETENT AUTHORITY REPORT EXCHANGE FORM (NCAR)**

*This form should be used for the exchange of medical device information between NCAR participants only. Completed forms should not be released to the public. All information contained in this form is considered confidential unless specifically indicated otherwise in section 3 or in the background section of the annex.*

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| 1. **CA Report Number:**<CA reference number>

[ ]  New[ ]  Amended |
| 1. **PURPOSE of the EXCHANGE:**

[ ]  **Share Information** [ ]  Events leading or highly likely to lead to unanticipated serious public health threat. [ ]  Observations from national trend analysis [ ]  Share Information as outlined in Section 4.1.3[ ]  Request Information[ ]  Summary of query findings  |
| 1. **Confidentiality/Distribution channel**

[ ]  Yes/**Restricted.** (The authoring NCA may share only with NCAR exchange program members with whom the NCA has confidentiality arrangements). [ ]  No/ **All** NCAR Exchange Program members.  |

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| **DETAILS OF INITIATING NCA** |
| 1. **Authoring NCA:**
 | <name of CA> |
| 1. **Contact Person:**
 | <name of contact person> | 1. **Telephone:**
 | <telephone number> |
| 1. **E-mail:**
 | <email address> | 1. **Fax:**
 | <fax number> |
| 1. **Circulated:**
 | <date circulated - dd/mm/yyyy> |
|  |  |
| **DEVICE DETAILS** |
| 1. **Generic name / kind of device:**
 |
| 1. **Nomenclature Type:**
 | 1. **No / Code:**
 |
| 1. **IMDRF Medical Speciality Area:**       **(list detailed in Annex 2).**
 |
| 1. **Trade Name and Model:**
 |
| 1. **Device also marketed as (trade name), if known:**
 |
| 1. **If Applicable, UDI #:**
 | 1. **Software version (If Applicable):**
 |
| 1. **Serial number(s):**
 | 1. **Lot / batch number(s):**
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| **Regulated Parties** |
| 1. **Manufacturer:**

      | 1. **Entity legally representing the manufacturer:**

      | 1. **If Applicable, CAB / Notified Body #:**

      |
| **Country:**       | **Country:**       |  |
| **Full Address:**       | **Full Address:**       |  |
| **Contact:**       | **Contact:**       |  |
| **Telephone:**        | **Telephone:**        |  |
| **Email:**        | **Email:**        |  |

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| **BACKGROUND INFORMATION AND REASON FOR THIS REPORT** |
| 1. <background of query / notification of lead CA>

Is the Investigation of the report Complete: [ ]  Yes [ ] NoAttachments: [ ]  Yes [ ] No (… include info re manufacturer/assembly location) |
|  |
| **QUESTIONS AND RESPONSES (If Applicable)** |
| 1. **Deadline For Response:** <date of deadline for response - dd/mm/yyyy>
 |
| **Question** | **Answer** | **Rationale / Remarks** |
| 1.
 |       |       |
|  |  |  |
| **ADDITIONAL RATIONALE AND REMARKS** |
| 1.
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|  |
| **DETAILS OF RESPONDING NCA** |
| 1. **Responding NCA:**
 | <name of CA> |
| **Contact Person:**  | <name of contact person> | **Telephone:** | <telephone number> |
| **E-mail:**  | <email address> | **Fax:**  | <fax number> |

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| **FINAL SUMMARY / COMMENTS** |
| 1.

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