|  |  |  |  |
| --- | --- | --- | --- |
|  | **devemed GmbH** | Tel: | +49 / 7467 / 94 91 99-0 |
| take-off GewerbePark 30 | Fax: | +49 / 7467 / 94 91 99-19 |
| 78579 Neuhausen ob Eck | E-Mail | [info@devemed.de](mailto:info@devemed.de) |
| Germany | Website | www.devemed.de |

**Reporting incident acc. article 87, MDR**

The aforementioned Article 87, MDR obliges us (devemed GmbH) as a manufacturer to report, among other things, any serious incident in connection with our products to the relevant competent authorities.

If you are aware of such an occurrence, we would like to ask you to fill out this form as completely as possible.  
(☝ all fields marked in red are mandatory fields!!!), send it to us and enclose it with the corresponding product. Fields that are not apllicable must be marked with „N/A“.

I In case of returning the form in advance of return of goods, please send it by mail to **incident@devemed.de**.

|  |
| --- |
| **2. Customer Information** |

|  |  |
| --- | --- |
| **Company:** |  |
| **Street:** |  |
| **Post code / City:** |  |
| **Customer-No.:** |  |
| **Contact Person:** |  |
| **Phone:** |  |
| **E-Mail:** |  |
| **Other reference numbers, if applicable e.g. order number** |  |

|  |
| --- |
| **2. Product Information** |

|  |  |  |
| --- | --- | --- |
| **REF / Article-No.** | **Item Description** | **Qty.** |
|  |  |  |
| **LOT-No.:** |  | |
| **Date Code:** |  | |
| **UDI:** |  | |
| **Expiration Date:**  **Only for sterile products** |  | |
| **Invoice No.:** |  | |
| **Delivery Note:** |  | |

**Additional Information (for implants only):**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Date of implantation** |  | **Date of explantation:** |  | **Duration of implantation (only if the exact dates are unknown)** |
|  |  |  |

**Accessories and / or with product connected devices (if applicable):**

|  |
| --- |
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| **3. Information to the incidents** |

|  |  |
| --- | --- |
| **Date on which the incident occurred:** |  |
| **Detailed description of incident:** | |
|  | |
| **Reference number of report of operator: (if known)** |  |
| **Quantity of affected persons: (if known)** |  |
| **Operator of the medical product at time of incident:** | |
| Professional operator | |
| Patient | |
| Others (please explain) | |
|  | |
| **Usage of medical product:** | |
| First practice / use | |
| Reuse of single use product | |
| Reuse of reusable medical product | |
| Damage, respectively problem recognized before operation | |
| Others (please explain) | |
|  | |

|  |  |  |
| --- | --- | --- |
| **Has the incident already been reported to an authority?** | | |
| Yes | No | N/A |
| **If yes, from whom?** | | |
| **Name:** |  | |
| **Address:** |  | |
| **If yes, to which authority?** | | |
| **Authority:** |  | |

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| --- |
| **4. Patient Information** |

|  |  |
| --- | --- |
| **Patient-Identification No.:** |  |
| **Gender (if relevant):** |  |
| **Weight (if relevant):** |  |
| **Date of birth:** |  |

|  |
| --- |
| **Short term and long term consequences of incident for the patient:** |
|  |

|  |
| --- |
| **Precautions of the health care facilities, which have been nessecarily required as a result of the incidence:** |
|  |

|  |
| --- |
| **5. Information to the health care facility, in which the incident has occurred** |

|  |  |
| --- | --- |
| **Name of facility:** |  |
| **Department:** |  |
| **Street:** |  |
| **Post code / City:** |  |
| **Name of reporter:** |  |
| **Function of reporter:** |  |
| **Contact person: (if not reporter)** |  |
| **Phone:** |  |
| **E-Mail:** |  |

|  |
| --- |
| **6. Date and Signature** |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **City:** |  |  | **Date:** |  |

|  |  |
| --- | --- |
| **Signature:** |  |

|  |  |  |
| --- | --- | --- |
|  | ***The following section is to be filled in by devemed!*** |  |
|  |  |

|  |  |
| --- | --- |
| **Name annehmender Mitarbeiter:** |  |

|  |  |
| --- | --- |
| **Datum der Kenntnisnahme:** |  |

|  |  |
| --- | --- |
| **Unterschrift:** |  |