|  |  |  |  |
| --- | --- | --- | --- |
| **1. Details of the reporting person** | | | |
| **Name of the contact person \*** |  | **Function \*** |  |
| **Company \*** |  | **Street, House No. \*** |  |
| **Postal Code \*** |  | **Location \*** |  |
| **Country \*** |  | **Telephone \*** |  |
| **E-Mail \*** |  | **Date of acknowledgement \*** |  |

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| **2. Details of the user** | | | |
| **Name of the user \*** |  | **Function \*** |  |
| **Location of the event \*** |  | **Street, House No. \*** |  |
| **Postal Code \*** |  | **Location \*** |  |
| **Country \*** |  | **Telephone \*** |  |
| **E-Mail \*** |  | **Date of acknowledgement \*** |  |
| **Details of wittness(es)\*** |  | | |

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| **3. Product Details** | | | | | | | |
| **Product name \*** |  | **SN/LOT-Nr. \*** | | |  | | |
| **Article number \*** |  | **Quantity claimed \*** | | |  | | |
| **The product is \*** | fully functional  limited functional  not usable | | | | | | |
| **Application situation \***  (Attach photos if possible) |  | | | | | | |
| **Will the product that is the subject of the complaint be returned? \*** | | | | | YES | | NO |
| **If „NO“, please**  **Specify reason. \*** |  | | | | | | |
| **4. Details of the event / problem** | | | | | | | |
| **Detailed description of the event/problem \***  (Attach photos if possible) |  | | | | | | |
| **Timing \*** | Before use  during use  after use | | | | | | |
| **Description of activities performed and/or measures initiated \*** |  | | | | | | |
| **Consequences \***  **(e.g., deterioration of health, death)** | No effect on patients.  No medical intervention or additional treatment of the patient necessary.  Medical intervention necessary (please describe any additional treatment and the patient's condition under "Other information").  Death of patient, user, or third person. | | | | | | |
| **Has a report been sent by the clinic to the appropriate authority? \***  If „YES“, please describe report number under „Other information“. | | | YES | NO | | Not known | |
| **Other information**  (optional) |  | | | | | | |

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|  | **Function** | Name | Date | Signature |
| **Reporting Person \*** |  |  |  |  |
| **Checked (Spiegelberg)** | **Quality Manager** |  |  |  |

Appendix – Instructions for filling in

**General**

This attachment serves as a guide for completing this reporting form. This attachment does not need to be submitted with the reporting form. You can fill in the form digitally (Acrobat Reader required) or by hand. Please make sure that you provide factual and formal information that is useful for understanding and evaluating the facts. The more precise and accurate your information, the faster the problem can be solved. All the information you provide in this report form should be comprehensible to a non-medical professional with knowledge of the product.

All fields marked with an asterisk "\*" are mandatory. Please do not leave any fields blank but enter "not applicable = NZ" or "not specified = KA" if appropriate. If the situation cannot be adequately assessed due to an inadequately completed reporting form, the reporting form will be rejected and must be supplemented by the reporting person. In this case, the corresponding national reporting deadlines defined by the legislator must be adhered to. The reporting person is responsible for this.

**Notes to fill in**

1. **Details of the reporting person**

The person who completed the reporting form. The information must be provided for any queries from a quality manager.

1. **Details of the user**

The person who applied the product when the problem occurred. The information must be provided for any queries from a quality manager. If the customer requests a final report by mail, this must be indicated under "Other information".

1. **Product information**

This section records all information about the product that is being claimed. Please describe the application situation in which the problem occurred. Also list all products that may be related to the problem. Please do not provide any information about the actual problem in this section.

Please note that a root cause analysis of the problem is only possible if the product is returned to Spie-gelberg. Send the product unchanged, in biologically sealed packaging. If this is not available, it will be provided by your Spiegelberg sales representative.

Please do not send products that have been in contact with a patient diagnosed with a dangerous infectious disease. In this case, coordinate any shipment with us.

1. **Details of the event/problem**

In this section, please describe in detail the problem or event that led to the complaint. Make sure that the description is complete so that the situation that led to the problem can be understood. This description serves Spiegelberg as a basis for initiating further measures.

Specify - if possible - the exact time when the error occurred. It is important to ensure that facts are stated and that there is no speculation about possible causes. For intracranial pressure measurement monitors, if available, please always include the error code (e.g., E1).

**Information on immediate measures carried out and definition of further necessary measures**

Please describe here any actions taken to correct the problem or implement a workaround and whether those actions were effective.

**Consequence information**

In this section, please provide information about the patient's condition and whether medical intervention was required because of the error.

**Other information**

Please provide any additional information here that may be helpful in processing the claim. In this section you can also indicate a suspected cause, describe the condition of the returned goods, or provide detailed information about the patient's condition.

**Completion and forwarding of the reporting form**

The report form is sent to complaints@spiegelberg.de by clicking on the "Send" button. The report form will be checked by a Spiegelberg quality manager upon receipt, and we will contact you immediately.

Alternatively, by fax to:

**+49 40 790178-10**