**Bob instruments GmbH**

Service department

Weilatten 3

D-78532 Tuttlingen

Germany

|  |  |
| --- | --- |
| **Customer-No.:** |  |
| **Company:** |  |
| **Department:** |  |
| **Street:** |  |
| **Postcode / Place:** |  |
| **Contact Person:** |  |
| **Tel.:**  |  | **Fax:** |  |
| **E-Mail:** |  |
| **Doc.-Ref.** |  | **Date:** |  |

**Information about the product:**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Item-No. / REF** | **Item description** | **LOT / Seral-No.** | **Bob instruments Invoice No** | **Date of invoice** | **Piece** |
|  |  |  |  |  |  |

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| **Unique Device Identifier (UDI information):** **(Which is indicated on the product, the product label or on the product packaging)** |
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| **Exact description of the defect:** |
| (e.g. marking of the product, sluggishness, corrosion at the lock etc. a simple does not work or no function is not sufficient and leads to delays and queries.) |

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| **Patients – results** |
| Was a patient involved? | [ ]  Yes [ ]  No |
| What happened to the patient? How´s the patient doing? |

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| **When was the malfunction discovered?** |
| [ ]  By the incoming inspection [ ]  By the functional test [ ]  In operation[ ]  Others: |

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| **Status of the medical device?** |
| [ ]  New [ ]  Used [ ]  Repaired |

If one or more questions answered with **YES,** the result is to perform a reporting obligation and further information´s are required absolutely necessary immediately. Please use the document **No. 7322 “Accompanying document -reporting of incidents”**, for Download [www.bob-instruments.de/extranet/](http://www.bob-instruments.de/extranet/) or please contact us immediately.

E-Mail: md.vigilance@bob-instruments.de

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| **Result of an Reporting obligation? (please check X)** |
| 1. Caused the contributed the product to a death of a patient or user?
 | [ ]  Yes [ ]  No [ ]  Unknown |
| 1. Caused the contributed the product to a serious injury\* of a patient or user?
 | [ ]  Yes [ ]  No [ ]  Unknown |
| 1. Caused the contributed the product to a serious deterioration of the medical condition of a patient, by a user or another person?
 | [ ]  Yes [ ]  No [ ]  Unknown |
| 1. Was a surgical intervention required to prevent or correct a serious injury\* to a patient or user?
 | [ ]  Yes [ ]  No [ ]  Unknown |
| 1. Caused or contributed a malfunction\*\* to a death or serious injury to a patient or user in the event of repetition?
 | [ ]  Yes [ ]  No [ ]  Unknown |
| 1. Is the product incomplete or are components and/or broken parts missing or have parts remained in the patient?
 | [ ]  Yes [ ]  No [ ]  Unknown |

**\*** **serious injury** means an injury or illness, that

1. is life-threatening,
2. resulted to a permanent handicap of a body function or a permanent damage to a body structure or
3. requires medical or surgical intervention, to exclude a permanent handicap of a body function or a permanent damage to a body structure. Permanent means, irreversible handicap or damage to a body structure or -function expect minor handicaps or Damage.

**\*\*** **MALFUNCTION** means the failure of a device to meet its performance specifications or otherwise perform as intended. Performance specifications include all claims made in the labelling for the device. The intended performance of a device refers to the intended use for which the device is labelled or marked. The term "malfunction" includes the following items:

1. failure
2. malfunction
3. Inappropriate or inappropriate design
4. Manufacturing error
5. Instruction for use (e.g. obscurities, incorrect content)
6. Failure in product or packaging marking
7. User error

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| **Other additional information:** |
|  |

I hereby declare, that

[ ]  the enclosed medical device(s) have been decontaminated (i.e., cleaned, disinfected and sterilized)

**CAUTION!**

[ ]  the enclosed medical device(s) have **not** been decontaminated.

|  |  |
| --- | --- |
|  | (Stamp) |
| Location |
| Name |
| Date / Signature |

**Important NOTE!**

We point out that without the required information (information) no report of the incident can take place.
**Please complete this form completely** and attach it to the product!

**Reference!**

Medizinprodukte-Sicherheitsplanverordnung MPSV:
<https://www.gesetze-im-internet.de/mpsv/>

EC MEDDEV Guidelines on a Medical Devices Vigilance System:
<http://ec.europa.eu/growth/sectors/medical-devices/guidance_en>

US FDA 21CFR Part 803 Medical Device Reporting
<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=803>

# Änderungshistorie

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| --- | --- | --- | --- | --- | --- |
| **Revision** | **Datum** | **Prozess-verantwortlicher** | **Datum** | **Freigabe** | **Beschreibung****der Änderung** |
| 02 | 01.06.2015 | QM/Rainer Müller/rm | 01.06.2015 | VK/Peggy Krell | AeA 051/15 |
| 03 | 09.01.2019 | QM/Anton Mittermüller/am | 09.01.2019 | GF/Joachim Schmid/js | AeA 130/18 |
| 04 | 13.03.2020 | QM/Anton Mittermüller/am | 13.03.2020 | QM/Rainer Müller/rm | AeA 044/20 |

**Revision:** Revisionsnummer im Format 00

**Datum:** Datum der Änderung im Format TT.MM.JJJJ

**Name:** Abteilung / Name / Kürzel des Autors der Änderungen

**Änderungen:** kurze Beschreibung der Änderung