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|  | **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 |

**Important Notes!**

* If you are planning to make a return due to a complaint, please take into account that this form must be filled out completely (☝ all fields highlighted in red are mandatory fields!!!) and returned to us together with the products complained. Incomplete information will lead to delays and queries or in the worst case that the complaint can not be processed or evaluated by us.
* Please fill out this form per article (item number). It is not allowed to enter several different item numbers.
* In the case of complaints due to instrument breakage, the broken parts must also be returned, as these parts are required for processing and evaluating the complaint. ⇨ see point 4
* For returns due to repair orders, please use the FB-099 Reshipment Form - Repairs.

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| **1. Information on decontamination / sterilization** |

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| --- | --- | --- | --- | --- | --- |
| Are the products still in their original packaging and/or unused? | | | Yes |  | No |
| Have the products already been used? | | | Yes |  | No |
|  | If you have selected **"Yes"**, we ask you to ensure that the products have been reprocessed prior to return and to **confirm the decontamination** with your signature! Products that have not been reprocessed will be returned to you unopened and freight collect. In case of non-compliance, you will be held responsible in case of damage. | | | | |
|  | Cleaning and Disinfection acc. to EN ISO 15883 |  |  | | |
|  | Optional: Sterilization acc. to EN ISO 17665-1 |  |
|  |  |  | **Date, Signature for confirmation decontamination**  We hereby confirm proper cleaning, disinfection and optionally sterilization according to national standards and guidelines | | |

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| **2. Customer Information** |

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

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| **3. Product Information** |

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

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| **4. Complaint Information** |

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| **Complaint number customer:** | | | **When was the defect detected?** | | |
|  | | | **Date:** |  | |
| **How was the defect detected?** | | | | | |
| at the incoming inspection: | | | | | |
| during functional testing (e.g. in course of reprocessing): | | | | | |
| during application/use: | | | | | |
| Other: | | | | | |
| **Detailed description of the defect:** | | | | | |
| (e.g. see marking on the product, heavy movement, joint corrosion, instrument breakage, etc.). Descriptions such as "does not work" or "no function" are not sufficient and lead to delays and queries and, in the worst case, to rejection of the complaint. | | | | | |
|  | | | | | |
| **Was a patient involved?** | | | | | |
| Yes | No | | | | |
| **If yes, what happened to the patient? How is the patient?** | | | | | |
|  | | | | | |
| **Do the claimed products all come from the same user?** | | | | | |
| Yes | No | N/A, as product was not yet in use | | | |
| **If No, how many different users do the products come from?** | | | | |  |

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| **Additional information in case of instrument breakage** |
| Please always return broken parts - if possible - with the product. A complaint can only be processed if the broken parts can also be inspected. In the event that broken parts cannot be returned, please state the reason below: |
| Broken part(s) has/have already been disposed of by the user |
| Broken part(s) is/are no longer detectable |
| Broken part(s) has/have remained in the patient |

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| **5.** **Reporting incident acc. article 87, MDR** |

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| Has the product resulted in an injury that has had, could have had, or may have had, directly or indirectly, any of the following consequences? | | | |
| 1. The death of a patient, user, or other person? | Yes | No | N/A |
| 1. A temporary or permanent serious injury to the health of a patient, user or other person? | Yes | No | N/A |
| b) if YES, please specify in more detail: (e.g. was there an extension of surgery? If so, by how many minutes?) | | | |
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| 1. A serious public health hazard? | Yes | No | N/A |

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| ☝ | If there is a reportable incident, further information must be provided immediately. Please also complete form **FB-098 Incident Report**.  This form is available for download at [www.devemed.de/service/](http://www.devemed.de/service/) under Forms! |

**Definitions:**

**„serious deterioration in the health“**

* life-threatening illness or injury
* permanent impairment of a body structure or a body function
* hospitalisation or prolongation of patient hospitalisation
* medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function
* chronic disease

*Reference: MDR, Article 2, No. 58*

**„****serious public health threat“**

means an event which could result in imminent risk of death, serious deterioration in a person's state of health, or serious illness, that may require prompt remedial action, and that may cause significant morbidity or mortality in humans, or that is unusual or unexpected for the given place and time

*Reference: MDR, Article 2, No. 66*

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| **6. Replacement delivery / Credit Note** |

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| Do you want a replacement delivery at cost before the completion of the complaint processing, which will be credited in case of a justified complaint. | Yes | No |
| Do you wish to receive a credit note or a free replacement after the completion of the complaint processing in case of a justified complaint? | Credit Note | Replacement |
| In case of an unjustified complaint, do you wish a replacement delivery with costs after the completion of the complaint processing? | Yes | No |

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| **7. Other additional information** |

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| **8. Date and Signature** |

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

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

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|  | ***The following section is to be filled in by devemed!*** |  |
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| --- | --- |
| **Name annehmende Person:** |  |

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

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