Checklist product return shipments for complaints of Bürki inno med AG products

To handle all forms of product returns, the following points need to be filled in and documents need to be sent in a complete manner (see below).

These requirements are based on the ongoing changes of EU legislations since the year 2016, which are mandatory in the EU territory and in Switzerland. Incomplete deliveries need to be sent back by us.

1. Full name and address, incl. contact person (incl. phone number and e-mail)

2. Name of signee

3. Product description, type, incl. batch no.

Mandatory requirements for all returned products (according the EU & Swiss-laws) are:

- **product must be cleaned, relevant protocol/proof added.**
- **product must be sterile/sterilized, relevant protocol/proof added.**
- **complete address added**

Complaint management

4. Detailed description of the occurrence (when?, who?, what?, how?, where?)

When? (precise time and date)

Who? (all involved persons)

What? (detailed description)

How?

Where?

5. Any damage to persons?

	No	Yes	Number of persons (all)	Specify individual damage of all damaged persons	Is the person with damage retraceable within the institution?
Patient (anonymized)					
Personnel					
Third parties					

6. Were immediate actions necessary?

- ☐ **Yes**
- ☐ **No**

If yes, please describe in detail

7. Were follow-up actions necessary?

- ☐ **Yes**
- ☐ **No**

If yes, please describe in detail

8. Did the occurrence lead to any delay of the surgical procedure?

- ☐ **Yes**
- ☐ **No**

If yes, please describe in detail the planned versus the actual surgical procedure

9. Processed (re-sterilized) instruments: quantity of processing cycles (incl. protocols)

Please specify the number of processing cycles that were already performed

10. Description of the cleaning process, including the cleaning agent

Date of the last validation of the cleaning process:

11. Description of the sterilization process

Date of the last validation of the sterilization process:

Please add copies of all certificates.

12. Final statement and signature

In case the involved products are not manufactured by Bürki inno med AG, Bürki inno med AG reserves its right to carry back the internal and external costs.

_____ _____

Date and place Name, signature and stamp of the organization

Declaration to the status of the hygiene and decontamination of returned products

Article description: _____
Article no./reference: _____
Batch no.: _____

Hereby I/we confirm/inform that the attached product(s) meet the below criteria (mark with a cross when applicable)

☐ **Contaminated product contains potentially infectious material, contaminants or pharmaceutical substances:**

Type of contamination: _____
Explanation: _____

☐ **The product was packed according ADR 2.2.62.1.5.9 (ADR: Accord européen relatif au transport international des marchandises Dangereuses par Route from Sept. 30th, 1957) or according the instruction OP 650 ADR.**

☐ **The following measures for risk reduction were undertaken:**

- ☐ **the product was drained and purged, the surfaces are dry and the openings are secured from leak.**
- ☐ **Cleaning according the manufacturer's instructions**
- ☐ **Disinfection**

Disinfection agent: _____
Exposure time: _____

- ☐ **Sterilization**

Sterilization method: _____
Exposure time: _____

☐ **No contamination with potentially infectious material, contaminants, or pharmaceutical substances.**

_____ _____

Date and place | Name, signature and stamp of the organization

_____ _____

Phone number / e-mail | Address of the organization