GM 18/8/18

Checklist product return-shipments for complaints of Bürki products

(QHB 08a4-12EN)

To handle all forms of product returns the following points need to be filled in and documents need to be send in a completely manner (see below):

These requirements base on the ongoing changing EU legislations since the year 2016, which are mandatory in the EU territory and in Switzerland. Uncomplete deliveries need to be send back by us.

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

2. Name of signee:

3. Product description, -type, inclusive LOT nr

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

- **product must be cleaned, relevant protocol/proof added,**
- **product must be steriled, relevant protocol/proof added,**
- complete address added

Complaint management

4. **Detailled description of the occurenmce (when, who, what, how, where)**

When (precise time & date)

who (all involved persons)

what (detailled description)

how

where

5. Any damages to persons?

	no	**yes**	Number of persons (all)	Specify indiviuall damage of all damaged persons	Is the person with damage retraceable within the institution?
Patient (anonymised)			…. …. …	…… ……. …….	
Personell				…… ……. …….	
Third parties				…… ……. …….	

6. Were immediate actions necessaire? Yes no

If yes, describe in detail

7. **Were follow-up actions necessaire?** **Yes** **no**

If yes, describe in detail

8. **Did the occurence lead to any delay of the ordinary OR procedure? Hat der Vorfall zu einer wesentlichen Verzögerung des regulären OP-Ablaufes geführt?**

Yes **no**

If yes, describe in detail the ordinary proceure versus the incurred one

9. Re-steriled instruments: Quantity of resterilisation cycles (incl. protocols)

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

Date of the last validation of the cleaning process

11. Description of the sterilisation process

Date of the last validation of the sterilisation process

Please add copies of all certifications.

In case the involved product(s) are not from Bürki, Bürki reserves it's right to carry back the internal and external costs.

place and date

signature & company stamp

Bürki inno med AG, Industriestr. 67, Widnau, Switzerland www.buerki.eu
GM, 26.8.2018

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

Article description: _____

Article-nr./REF: _____

Lot nr.: _____

Hereby I/we confirm that attached product(s) fulfil all requirements (mark with a cross)

☐ **contamineted product containes potentially infetious material, contaminants or pharmaceutical substances:**

typ 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 _____

Residence time: _____

☐ Sterilisation
employed procedure: _____

Residence time: _____

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

Date: _____ Signature : _____

Name of signee in printing: _____

Telephon: _____ E-Mail: _____

Name & Address-stamp of sending institution: