


Incident Report

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Reportable Incident acc. to MPSV § 3 Medizinprodukte-Sicherheitsplanverordnung MPSV: www.gesetze-im-internet.de/bundesrecht/mpsv/gesamt.pdf	

Customer data			
Customer ID:	_____	Street:	_____
Company:	_____	ZIP/ City:	_____
Department:	_____	Country:	_____
Contact Person:	_____		
E-Mail:	_____		
Phone:	_____		

Product information			
Item no.:	_____	Item description:	_____
Date of Invoice:	_____	Invoice No.:	_____
Delivery note:	_____		
Nomenclature system:	_____	Nomenclature code:	_____
Quantity:	_____	LOT/ Serial No.:	_____

- Reasons:**
- | | | |
|--------------------------------------|---|---|
| <input type="checkbox"/> Reclamation | <input type="checkbox"/> wrong Delivery | <input type="checkbox"/> Return takes |
| <input type="checkbox"/> Repair | <input type="checkbox"/> Cancellation | <input type="checkbox"/> Others (please describe) |

Accessories and/ or with product connected devices (if applicable):

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Information to the incident:

Detailed description:

Reference number of report of operator (if known):

Quantity of affected persons (if known):

Operator of the medical product:

- Professional operator
 Patient
 Others (please explain)

Usage of the Product:

- First Use
 Reuse of a single use product
 Maintained respectively repaired medical product
 Reuse of a reusable medical Product
 damaged/ not usable medical Product
 Others (please explain)

Patient information (possible consequences of the Incident):

Precautions of the health care facility, that have been necessarily required as a result of the incidence:

Information to the health care facility			
Name of facility:		Street:	
Department:	<hr/>	ZIP/ Ort:	<hr/>
Contact person:	<hr/>	Country:	<hr/>
Phone:	<hr/>		
E-Mail:	<hr/>		

Notice:

We point out that no announcement of the incident can be affected without the required information. Please fulfill this document complete and attach it to the product.

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Ort/ Datum: _____

Unterschrift: _____