Titel / Title: **Medical Devices Vigilance Report Form**

If available:

K-number: K- _____ **SAB number: SAB**_____ **RET- number: RET-**_____

1. Data on the reporting person - All fields are mandatory fields/evaluation of non-filled fields with n/a			
Name of the reporting company		**Debitor number** (if known)	
Name of contact person		**Function**	
Street, house no. or P.O. Box			
Postal code		**City**	
Country			
Phone		**FAX**	
E-Mail		**Date of knowledge**	

2. Details of the product – All fields are mandatory fields/evaluation of non-filled fields with n/a					
Name of ulrich product				**Quantity claimed**	
Article number of the implant/instrument/device		**Software-version** [1]		**SN / Lot no.**	
Article number of the faulty part (Fault location) [1]		**Description** [1]		**SN / Lot no.** [1]	
Application situation, other products involved *as detailed as possible and with photo*					
Is the product [1]	☐ fully functional	☐ limited functional		☐ not usable	

[1] To be filled in only if the product in question is a device.

3. Details of the event / problem - All fields are mandatory fields/evaluation of non-filled fields with n/a			
Detailed description of the event/problem *(as detailed as possible and with photo)*			
When did the problem occur	☐ before application	☐ during the application	☐ after application
Frequency of the problem		**Device error code** [1]	

[1] To be filled in only if the product in question is a device.

How long has the product been in use? [2]		**Approximately how often was the product used?**[2]	

[2] To be filled in only if the product in question is a device or an instrument.

Message was taken as follows	☐ on site (at the user)	☐ by phone	☐ by Email	☐ other

If available:

K-number: K- _____ **SAB number: SAB**_____ **RET- number: RET-**_____

Description of activities carried out and/or measures already initiated *(if applicable)*	
Is the product fully functional again after the activities performed?	☐ yes ☐ no
What is specifically required/requested from ulrich medical?	☐ Repair ☐ Credit note/ free replacement ☐ chargeable replacement ulrich invoice number of the original delivery: Other:
Formal statement to the customer required?	☐ yes ☐ no
Defective/complained Article	☐ is enclosed ☐ will be resent ☐ not available ☐ n/a
Log files saved [1)]	☐ yes (please send in with the notification) ☐ no ☐ n/a
User's report/complaint letter	☐ is enclosed ☐ will be resent ☐ not available ☐ n/a

4. Other additional data/information on the event/problem
(In the case of devices, the following must be stated here if known: accessories used, consumables used with batch number, level of knowledge of the user who was operating the device at the time of the event)

5. Further information on the complaint and/or the reportable incident – mandatory field
Reporting deadlines under point 7 are to be observed without fail

Effects (e.g. death, deterioration of health)	☐ No impact on patient ☐ Patient briefly under observation, patient unremarkable, no medical intervention necessary ☐ Medical intervention necessary, indication of the patient's state of health under "Additional information". ☐ Effects on users or third parties, please provide detailed information under "Additional information". ☐ Death of the patient please specify under "Additional information".
Additional information (if necessary)	

The first contact must check whether his message has been transmitted correctly and completely. He is responsible for ensuring that all necessary data is immediately available to the internal service or the technical service.
--> see for this **Reporting deadlines and contact persons under point 7**

If available:

K-number: K- _____ **SAB number: SAB**_____ **RET- number: RET-**_____

6. Information on the user - All fields are mandatory fields/evaluation of non-filled fields with n/a			
Clinic/practice of the event		**Debitor number** *(if known)*	
Name of contact person		**Function**	
Street, house no. or P.O. Box		**Postal code**	
City		**Country**	
Phone		**Occurrence date**	

[3] Only to be filled in if known

Name of the person on duty/treating physician [3]		**Function** [3]	
Name of witnesses [3] *(if applicable)*			

Was a report sent from the clinic to the responsible authority:

☐ yes ☐ no ☐ not known

7. Reporting deadlines and contact persons

Reporting deadlines:

In the event of an incident resulting in death or a potential hazard to public health

- ⇨ **Immediately** inform the ulrich medical **safety officer by telephone**
- ⇨ Subsequently, submit the complete report form to ulrich medical

In case of other malfunctions or defects

- ⇨ Immediately, but **within 72 hours** at the most, send the complete report form to ulrich medical.

	Contact adress **Medical Device Vigilance Report**	Contact adress **Safety Officer**
Implants or instruments:	complaint@ulrichmedical.com	a.hilzenbecher@ulrichmedical.com Mobil: +49 151 19 02 5886
Devices	service@ulrichmedical.com	s.erdmann@ulrichmedical.com Mobil: +49 173 92 97 659

Place, date	Signature of the **reporting** person
Place, date	Signature of **the QM - employee ulrich medical**

The following section is **only to be completed by ulrich medical employees** who have been trained in accordance with AA-02-04-01_DE and § 83 MPDG.

This section only needs to be completed if the product being claimed is **a device or consumable for a device**.

8. Decision tree for safety officers (SiBa) Assessment*		
A. Death of the patient or user or third party	☐ YES	☐ NO
B. Serious illness or injury to the patient or user or third party.	☐ YES	☐ NO
C. Possibility of death and/or serious illness of patient, user or third party.	☐ YES	☐ NO
D. Item does not meet the labeling or packaging requirements	☐ YES	☐ NO
E. Service request with warranty claim	☐ YES	☐ NO
F. Service request without warranty claim	☐ YES	☐ NO

All fields are to be marked with YES/or NO.

If one or more of the points A - D apply, sections 6 and 7 must be completed on the notification form (FB-02-04-03_EN) in accordance with the Medical Device Law Implementation Act and must be forwarded to ulrich medical within the corresponding deadlines (event resulting in death or a potential risk to public health - immediate telephone notification, other malfunctions or defects - immediate notification within a maximum of 72 hours)!

Place, date	Signature of the **employee ulrich medical**
Place, date	Signature of **the QM - employee ulrich medical**

General

Important note

This appendix serves as a guide as to how the form must be completed. However, it is not to be considered part of the reporting form and does not need to be submitted as part of a report.

General tips: The reporting form must be completed in a factual and formal manner. Emotional statements will result in rejection of the reporting form.

Filling out the report form requires a certain amount of time and effort, which we are aware of and which must be carried out by everyone who receives a report in order to ensure that the complaint is processed in a targeted and optimal manner. The more precise and accurate the information about the problem is, the faster the problem can be solved. Fields that are not filled in must not be left blank, as they will be considered "forgotten" by the FDA. "n/a" must be entered here.

Insufficiently filled in reporting forms will be rejected immediately and must be completed accordingly by the reporting person. In this case, it is imperative to comply with the reporting deadlines defined by the legislator. The reporting person is responsible for complying with the statutory deadlines.

Filling out the reporting form

1. **Information on the reporting person**

This section captures the information about the person making the report. Please fill out the section completely. This information is needed for any queries about the complaint case

2. **Product information**

This section captures the information about the product that is being claimed. Please fill out the section completely.

Field "Situation of use":

The information in the field "Application situation, [...]" **must** be described in such a way that it can be understood and understood by a third party who has sufficient knowledge of the product. This field must list, as far as possible, **all** products that were used in connection with the ulrich medical product or may be related to the problem/incident.

If applicable, please include the date of the last maintenance (STK) or repair performed by an ulrich medical employee or an authorized technician. This information is important for the correct assignment of responsibilities in the event of an incident as defined by the MDR. If this information is not available, it must not lead to a delay in reporting. In these cases, the information can also be submitted later..

Example withXD 8000:

In the case of a complaint about the injector (XD 8000), information must be included on the serial no. of the device, the pump hose (XD 8003 + LOT no.), the patient hose (XD 20xx + LOT no.), the contrast medium used (clear, complete description of the KM, as well as the information "preheated" or "cold"), the saline solution (clear, complete description), and the software version that was installed at the time of the problem. Information about the scanner (manufacturer and model) and the type of examination performed (e.g., mammography).

1) marked fields are to be filled in ONLY if the device is.

3. Details of the occurrence / problem

This section records the information about the problem or incident that leads to the complaint. The problem must be described in such a way that the information can be understood and comprehended by a third party with sufficient knowledge of the product and that a clear, holistic picture of the situation that led to the problem emerges. This description is the basis for the safety officer's decision to initiate further measures, such as a report to the appropriate country authorities up to and including a recall, as well as for downstream activities within the complaint process.

If possible, please indicate the time and date of the error case. Furthermore, please indicate whether the problem
- before the application
- during the application
- after the application

occurred.

Be sure to reflect only the facts that were reported or observed and do not speculate on possible causes. For equipment, the error messages issued by the equipment should be noted.
The contents must be reproduced in a factual form, without emotional comments. In addition, a note must be included as to whether the complaint was taken in person on site, by telephone, by email, etc.

Information on immediate actions taken and definition of further necessary actions.

This section captures information about the actions taken and/or initiated by the employee to correct the problem or implement an emergency remedy.
These measures must be described in such a way that the information can be understood and comprehended by a third party with sufficient knowledge of the product and that a clear, holistic picture of the measure emerges. In addition, it must be stated whether the measure is effective.

The contents must be reproduced in a factual, formal form.

4. Information on "other additional data/information“

This section must describe the next/necessary steps that have been agreed with the user and must be processed as part of the complaint:
- How should the customer be informed about the further measures outside the complaint?
- What measures must be taken at the customer's site as part of the complaint?
- How must the customer be informed about the completion of the measures (ADM/QA/TS)?

For complaints involving implants: In the case of postoperative implant failure, FB-02-04-09_DE_EN must be completed in addition or obtained from the user and attached to the reporting form or noted on the reporting form if form 02-04-09_DE_EN is submitted subsequently.

5. Information on consequences

This section captures the information about the patient's condition in case of injury or medical intervention (see definition "Incident").

The **consequences** section is a required field and must not be left blank. One of the following must be provided:
- no effect on the patient
- patient briefly under observation - patient unremarkable - no medical intervention necessary
- medical intervention necessary (What is the patient's state of health? Where is the patient?)
- Impact on user or third party (Has a user or third party been harmed or was there a risk of this happening).
- Death of the patient

Information on "Has a report been sent by the clinic to the competent authority".

This section captures the information whether a "reportable event" was suspected by the clinic or user and a report form was sent to the competent authority according to MDR.

6. Information about the user

This section is a mandatory field. It captures the information about the customer. Please provide the complete information we need to contact the customer for further information and to prepare a final report for the customer after the complaint has been closed (if the information "Customer expects to receive a written response" was noted in the notification).

7. Information on "reporting deadlines and contact persons"

This section captures information on the time window within which the report must be forwarded and who must be notified immediately.

8. This section may only be filled in by employees of ulrich medical who are trained according to § 83 MPDG.

9. Completion and forwarding of the form

The form should be signed by the reporting person, with date and place. If the form is transmitted in digital form, it must be signed by a QM employee after it has been checked for plausibility.

The plausibility check is carried out for each reporting form sent in. If the information has not been provided completely and in accordance with the instructions, the complaint will not be accepted. It is imperative that this instruction is followed, as all discrepancies can have serious consequences. The applicable reporting times must always be observed and complied with.

The form must be sent to the following email address:
complaint@ulrichmedical.com