An incident according to Regulation 2017 / 745 MDR Art. 87 is a malfunction or deterioration of the characteristics of a product already made available on the market. This also includes application errors due to ergonomic features, the inadequacy of the information provided by the manufacturer or undesirable side effects.

1. Date of reporting:	_____
2. Details of the person reporting	
Name of the institution / practice / company:	
Title / name / first name of the contact person:	
Address: Street + house no.: ZIP CODE: Location: Country: Telephone: E-mail:	
3. Information on the Medical Device	
Product name:	
Item number / catalog number:	
Batch / serial no.:	
4. Details of the incident	
Date when the incident occurred:	
Detailed description of the incident:	
To which competent authorities was the incident also reported (European and international)?	
Where is the medical device now?	
4.1. Details of the intervention:	
With which devices / equipment was the product used?	
Have any persons been harmed?	

5. Confirmation of the data

Please take into account that we can only process fully completed forms in a timely manner.
The following signature confirms that all information provided in advance is complete and corresponds to the actual circumstances.

Name:	Date:	Signature:

Please send the **completed** and signed form by e-mail to: **medical-device-safety(at)stoma.de**