Annexes 

# Annexes

## Annex 1: User feedback form

Send feedback to: manufacturer and their local economic operator and as soon as you become aware.

Types of feedback:

* + **Death or serious deterioration in health** of the patient/client, user or any other person *occurred*.
	+ **Death or serious deterioration in health** of the patient/client, user or any other person *might have occurred.*
	+ **Positive feedback** may include suggested improvements, positive experiences, etc.

##### List of medical device product problems that should be considered for feedback

* + Patient-device incompatibility
	+ Manufacturing, packaging or shipping
	+ Chemical
	+ Material integrity
	+ Mechanical
	+ Optical
	+ Electrical/electronic property
	+ Calibration
	+ Output, e.g. false negative or false positive result for an IVD
	+ Temperature
	+ Computer software
	+ Connection
	+ Communication or transmission
	+ Infusion or flow
	+ Activation, positioning or separation
	+ Protective measure
	+ Compatibility
	+ Contamination/decontamination
	+ Environmental compatibility
	+ Installation-related
	+ Label, instructions for use or training
	+ Human-device interface
	+ Use of device
	+ Adverse event without identified device or use

*Note:* this is not an exhaustive list of potential user feedback.

**** Guidance for post-market surveillance and market surveillance of medical devices, including in vitro diagnostics

##### Contact details of the reporting user (organization/person)

|  |  |
| --- | --- |
| Name of organization:      | Street name and no.:      |
| City and postcode:      | Country:      |
| Name of contact person (for organization):      | Mobile telephone of contact person (for organization):      |
| Position of contact person (for organization):      | E-mail of contact person (for organization):      |
| Report date:      | Reporter’s report identifier:      |

##### Product details

|  |  |
| --- | --- |
| Product name/commercial name/brand name:      | Product code/catalogue number(s):      |
| Serial number(s):      | Model number(s):      |
| Lot number/batch number(s):      | Expiry date(s):      |
| Instructions for use version number:      | Software version number:      |
| Associated devices/accessories (lot numbers/expiry dates):      | UDI-DI/UDI-PI:      |
| Manufacturer name:      | Authorized representative name:      |
| Manufacturer contact details (e-mail):      | Authorized representative contact details (e-mail):      |

Please attach a copy of the instructions for use and photographs of the device and its labelling.

##### Event details

Annexes





|  |
| --- |
| Describe the clinical/analytical procedure during which the observation was made (note: in the case of IVD, state specimen type used):      |
| Event description (e.g. in the event of negative feedback, explain what went wrong with the medical device, and what was the health impact [death, life-threatening, indirect harm such as misdiagnosis or delayed diagnosis/treatment], and in the event of positive feedback, explain suggestions for improvement or positive experiences):      |
| Date of observation/event was made:      | % of devices involved:      |
| Number of devices involved:      | Number of patients involved:      |

|  |  |
| --- | --- |
| Operator/user at the time of the observation/event (please choose):[ ]  Health care professional [ ]  Patient/lay user[ ]  Other (specify): | Has more than one user had the observation with the product?[ ]  Yes [ ]  No |

|  |
| --- |
| Comments:      |
| Date of report:      | Signature:      |

**Disclaimer:** The act of reporting an observation is not an admission of manufacturer, user or patient liability for the event or its consequences.

