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.

