## 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.

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

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

##### Product details

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

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

##### Event details

|  |  |
| --- | --- |
| Describe the clinical/analytical procedure during which the observation was made (note: in the case of IVD, state specimen type used):  Click here to enter text. | |
| 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):  Click here to enter text. | |
| Date of observation/event was made:  Click here to enter text. | % of devices involved:  Click here to enter text. |
| Number of devices involved:  Click here to enter text. | Number of patients involved:  Click here to enter text. |

|  |  |
| --- | --- |
| 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:  Click here to enter text. | |
| Date of report:  Click here to enter text. | Signature:  Click here to enter text. |

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

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