Bijlage E: Notification of deviations in quality/Recalls

Summary Recall procedure (version Handbook 5060 dated 01-05-2019)

As a result of a quality deviation of a medical device used at UMC Utrecht, as indicated by the supplier or internal user, the recall procedure is carried out by retrieving a medical device (MHM) that may or may not be used from the organization, which pose a potential danger to the patient care.
A safety message issued by the supplier can make the UMC Utrecht decide to also carry out a recall if the risk and the guarantee of the risk is such that the safety of the patient (s), employees and / or the UMC Utrecht is insufficient

In addition to the recalls, the recall procedure also includes safety messages, field saftey notices et cetera.

Register recall by supplier
The supplier reports the notification of the recall to the coordinator medical devices and purchasing team at the following email addresses:
MeldpuntInkoop-2@umcutrecht.nl en inkoopmedisch@umcutrecht.nl.

The notification is then carried out by the coordinator medical devices.

For the adequate and guaranteed execution of the recall, the supplier must provide at least the following information;

- **Lot/chargenumber**
- **Supplier's article number**
- **PO number(s) UMC Utrecht**
- **If necessary, a safe comparable alternative to the product (sample and specifications supplied by supplier and verification by assortment coordinator, for patient safety)**
- **Recall form/supplier notification**
- **Contact person and data supplier**

Without the above requested information it will not be possible to process the recall.

Review recall
The coordinator medical devices of UMC Utrecht assesses the extent to which the recall has an impact and consequences on UMC Utrecht.

The coordinator medical devices decided in consultation with the recall team whether or not the recall will ultimately be carried out and in what form.

If the recall is not or cannot be carried out for certain reasons, as opposed to the supplier's request, the supplier will be informed.
The recall team also assesses the consequences and measures to be taken for recall products that have already been used, used and / or implanted by patients.
In addition, the recall team makes a decision about whether or not to use the (possibly) offered alternative and initiates an (urgent) order procedure.

If the recall has no impact on UMC Utrecht, the procedure is terminated, the coordinator medical devices will send a notification of this decision to the supplier.

If the recall does have an impact on UMC Utrecht, the organization will be informed by the coordinator medical devices in such a way that the recall can be carried out adequately and patient safety is guaranteed

Returning / retrieving recall products
The recall products are returned or picked up by the supplier in consultation with the logistics department and the coordinator medical devices and where possible replaced by the correct product, stating a corresponding UMC order number. If credit is involved, this will also be done with reference to the UMC order number.

The logistics department performs a counting and registration of the products and this is recorded in the supplier's recall form.

End of recall procedure
The recall is finalized by the coordinator medical devices through the supplier's recall form.

All actions and decisions taken are recorded in writing by the assortment coordinator in a file in the UMC Utrecht system.