



questionnaire

Standard questions medical devices and in vitro diagnostic devices

Product characteristics

- 1 Commercial name of the product;
- 2 Name, address, telephone and fax number of the manufacturer (or authorized European representative) and the name of the relevant contact person;
- 3 Description of the activity and intended purpose of the product, as stated in the instructions for use and/or promotional material;
- 4 Model and/or catalogue number;
- 5 Serial and/or lot number;
- 6 Identification of the product according the GMDN code (Global Medical Device Nomenclature);
- 7 EC code according to EN ISO 15225 (for in vitro diagnostic devices the code is always 06);
- 8 Classification of the product according to the Directive (please quote the applicable classification rule);
- 9 If applicable the identification number of the involved notified body;
- 10 If applicable, the version number of the software used with the product;
- 11 Other equipment, accessories, drugs or materials that are implicated in the incident.

The situation in the Netherlands

An FSCA regarding a product from your company was reported to us. As the Dutch Health Care Inspectorate is also the supervisory service for health care institutions in the Netherlands, we are also entrusted with supervision and law enforcement for the application of medical devices and IVDs. Therefore, it is essential you provide us with this information. Please, provide us with all the requested information directly, even if you have to retrieve this information elsewhere (i.e. a local distributor).

- 12 If the product is available on the Dutch market? If so, which Dutch hospital(s) or institution(s) is/are affected and how many products are involved?
- 13 Have problems similar to the ones reported occurred (elsewhere) in the Netherlands?
 - a *If no problems or incidents occurred, the following questions can be ignored, then go to question 23.*
 - b If so, where?
- 14 Has this led to any loss or injury to patients (e.g. improper treatment or no treatment at all, permanent damage, death, etc.)?
- 15 Has this led to any risk of loss or injury to persons other than patients (e.g. health care workers)? If so, describe the nature of the losses/injuries in question.
- 16 Date of (near) incident/complaint;
- 17 Location of the (near) incident/complaint;
- 18 Clear description of the (near) incident/complaint;

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- 19 Name and address of the organisation (health care institution) which reported the matter to the manufacturer;
- 20 Date on which the incident/complaint was reported to the manufacturer;
- 21 Current location of the product in question;
- 22 If available, reference number(s) assigned by the DHCI.

Actions and measures

- 23 In case of a problem with an in vitro diagnostic medical device: is it necessary to retest patients? If this has been done already, were there any discrepancies?
- 24 Description of corrective action. If applicable, please provide a copy of the Field Safety Notice, etc.;
- 25 What measures have been taken by the manufacturer or authorized representative (whether or not the product is available on the Dutch market)?
- 26 Finalisation (a or b):
 - a In case of an FSCA: confirmation as soon as the corrective action/recall has been completed in the Netherlands.
 - b In case of an incident: expected date of follow-up and/or final report.