## Reporting of EC Vigilance to SGS

**Introduction**

It is a legal and contractual requirement to inform SGS of all EC Vigilance Reports at the same time as reports are sent to the European National Competent Authorities (CA) by you the manufacturer (or your European Authorised Representative if they have been given this task). This is to allow SGS as Notified Body 0598 to review any implications on future auditing of your quality management systems and in some cases to review the implications to your certification. It is not the role of Notified Bodies to follow each incident so in many cases we will review your reports but not need to contact you.

**Reporting**

Manufacturers shall meet the requirements MDR (EU) 2017/745. Manufacturer shall report to the CA of the Member States in which the incident occurred throught the electronic system on vigilance and on post market surveillance. Copy of the electronic report must be sent to SGS Fimko Notified Body 0598 (nbmed.fimko@sgs.com) with following information: report of trends, PSUR, field safety notice by manufacturer, UDI of the products.

If the the electronic system on vigilance and on post market surveillance is not available, please check the guidance of your competent authority on the required reporting method.

Please complete this form and send it electronically with copies of EC Vigilance Reports to the [nbmed.fimko@sgs.com](mailto:nbmed.fimko@sgs.com) address as well as to the CA of the Member States in which the incident occurred.

**Notes:**

1*. Follow up* incident reports should not be sent unless requested.

2. Do not use this form to notify SGS of adverse event reporting where this was only outside Europe.

**SGS Review**

SGS will review each form and its attachments and if necessary contact you with further actions. The details of this review and any required action are documented in the **Review** section at the end of Part 1. However, in all cases of Vigilance, it is important that the manufacturer investigates and submits a Final Incident Report as soon as technically possible to the Competent Authority CA of the Member States in which the incident occurred and to SGS.

**PART 1**

**To be completed by the Manufacturer**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Manufacturer Name: | |  | | | | | | | | Date: | |  | |
| Contact for EC Vigilance Name (Person responsible for regulatory compliance) : | | | | | |  | | | | | | | |
| Note: In some cases this could be the Authorised Representative. | | | | | | | | | | | | | |
| Contact Tel: |  | | | | | | | E-mail: | | |  | | |
| Current SGS MDR Certificate Numbers: | | |  | | | | | | | | | | |
| Product UDI : | | |  | | | | | | | | | | |
| Registration in Electronic system on vigilance and PMS | | | N/A    Done on the *(date)* \_\_\_\_\_   Will be done on the *(date) \_\_\_\_\_* | | | | | | | | | | |
| Vigilance Report Type (as defined in MEDDEV 2.12-1)  Incident Report  FSCA Report  Periodic Safety Update Report  Trend Report | | | | | | | | | | | | | |
| Initial  Final  Combined | | | | | | | | | | | | | |
| 1. Please email as attachments this form in WORD format and the EC Vigilance Report(s) in WORD or pdf format.  2. Please email your normal local SGS office.  3. Please keep the total email size below 12 MB to ensure successful transmission.  4. Please do not send Follow Up reports | | | | | | | | | | | | | |
| Has this Incident already been reported to SGS ? | | | | Yes  No | | | If Yes | | **Your Vigilance Ref No:** | | | |  |
| Have you already been instructed by a Competent Authority to take action? | | | | | | | | | | | | | Yes  No |
| If Yes what action has been agreed: | | | | |  | | | | | | | | |

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**To be completed by SGS Fimko**

|  |  |
| --- | --- |
| **Date of next scheduled audit** |  |
| **Type of visit** |  |

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### SGS Review

|  |  |
| --- | --- |
| **The result(s) of the SGS review are shown below indicated by X**. | |
| No specific action because vigilance case is clearly not related to the certification granted but to be followed up as part of auditing Vigilance at the next scheduled SGS audit.  Justification : |  |
| Request the manufacturer to inform SGS about the results of investigation and review the risk on certification by assessing corrective ation taken. |  |
| To be followed up at the next scheduled SGS audit but manufacturer requested to take the following action. No further information is required by SGS at this stage. |  |
| Details of Action: |
| Please send the following information to nbmed.fimko@sgs.com as soon as possible. |  |
| Details of Information Required: |
| Your local SGS Office will be contacting you directly as SGS consider some urgent action or information is required. |  |
| Your local SGS office will be contacting you to arrange the date of an unscheduled audit to follow up your investigation of this incident(s). |  |
| Please send a copy of the technical file for the device shown to your local SGS office for review. |  |
| Details of Technical File(s): |
| Is there a need to use the SGS Fimko Internal Clinician to review the vigilance data? | Yes  No |
| Other Action Required |  |
| Details of Other Action Required: |

|  |  |
| --- | --- |
| Vigilance Review by SGS Fimko | |
| SGS Fimko  Date and Name: |  |

When specific client action is required a copy of PART 1 of this form will be emailed to the client Vigilance contact and the local SGS person handling the case by the SGS Fimko.

**END OF PART 1**

### PART 2 FOR SGS USE ONLY

### SGS Administrative and Auditor Information

|  |  |  |
| --- | --- | --- |
| SGS Department Code and Contract No: |  | |
| **The internal SGS actions for the SGS local office are indicated by an X below .** | |  |
| Archive on client folder and audit planning matrix for auditor review prior to auditing Vigilance at next scheduled audit. | |  |
| Archive on client folder and audit planning matix for review by auditor at next scheduled audit with instructions to auditor. | |  |
| Details of Instructions to Auditor:  Review the complete vigilance file to assess risk of certification:  Review specific process : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Review technical file and specifically following point :\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | |
| Contact client to arrange an urgent unscheduled audit. | |  |
| Details of Unscheduled Audit: | |
| Contact client to Arrange technical File review. | |  |
| Details of Technical File Review: | |
| Schedule an unannounced audit – **do not contact the client**. | |  |
| Details of Unannounced Audit: | |
| Plan product testing – **do not contact the client**. | |  |
| Details of test plan | |
| Contact the client to increase frequency of surveillance audit - | |  |
| Details of surveillance activities concerned including new frequency : | |
| Contact client to inform them of certificate suspension or withdrawal. | |  |
| Details of certificate suspension or withdrawal: | |
| Please take the specific actions detailed below. | |  |
| Details of Action Required: | |

|  |  |
| --- | --- |
| Vigilance Actions reviewed by SGS Fimko | |
| SGS Fimko  Date and Name: |  |

Following review by SGS Fimko this form must be:

- Approved on if no further action is required

- Queried on if local action is required

- Held on whilst SGS Fimko actions are taken

END OF PART 2