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Med-Info

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for the medical device industry

Medical device vigilance – obligations to report to the Notified Body

The manufacturer or the authorised representative is obliged to inform TÜV SÜD of every vigilance cases, which are:

- serious incidents,
- serious public health threats,
- unanticipated serious deterioration in a person's state of health,
- death.

In addition, these vigilance cases must meet the following criteria:

- Devices are EC/EU-certified by TÜV SÜD Product Service GmbH.
- They possibly caused the vigilance case, e.g. through insufficient labeling.
- They have been reported to EU authorities by the manufacturer.

Furthermore, Field Safety Corrective Actions must be reported, which meet the following criteria:

- The measures have been taken in third countries.
- The reason for corrective action is not limited to the third country.
- They are related to devices, which are EC/EU-certified by TÜV SÜD Product Service GmbH.
- They have been reported to EU authorities by the manufacturer.

If such cases happen on a recurrent base, there is the option to agree with the authorities on a Periodic Summary Report.

Relevant reports:

- Manufacturer Incident Reports (MIR)
- Field Safety Corrective Actions (FSCA)
- Field Safety Notices (FSN)
- Periodic Summary Reports (PSR)
- Trend Reports

The reporting conditions are established in the Testing and Certification Regulations (TCR) and are specified in the respective application forms for certification (MDD/AIMDD/IVDD or MDR/IVDR). These documents establish the contractual agreement regarding vigilance reporting between the legal manufacturer and the Notified Body TÜV SÜD Product Service GmbH. Please note that reporting to TÜV SÜD does not affect other regulatory vigilance-reporting obligations of the manufacturer or authorised representative.

These requirements are defined in the EU regulations and EC directives on medical devices, MEDDEV 2.12-1 rev. 8, NBOG BPG 2009-2, the German Act on Medical Devices (MPG) and related ordinance (MPSV) as well as in the rules of the German Designating Authority (ZLG).

Please send us the relevant EC or EU certificate number, the manufacturer name as on the EC/EU certificate and product name as provided on the list of CE-marked devices with each vigilance report (initial/follow-up/final) in PDF and XML format. Please enter the certificate number in the appropriate field, if possible or otherwise separately. All vigilance information shall be submitted to the following address: **mhs-vigilance@tuvsud.com**.

Please note that the assessment of vigilance information is a billable service since 2020. For each assessed vigilance case we thus charge a general fee.

Depending on the submitted data, the vigilance assessment process may require involving various specialists. Arising costs will be charged as stated in the order confirmation. The full extent of the work required cannot be determined at this stage since additional activities may be needed during the assessment. In this case, the fees outlined in the schedule of services and prices of TÜV SÜD Product Service valid at the time of the assessment will apply.

If you have any questions, do not hesitate to contact your client manager at TÜV SÜD Product Service.

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