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Medical device vigilance – obligation to report to the Notified Body

What to report to TÜV SÜD Product Service GmbH?

With effect from the dates of application of Regulations (EU) 2017/745[1] and 2017/746[2] (MDR and IVDR), the requirements relating to post-market surveillance and vigilance, in accordance with MDR Art. 120 (3) / IVDR Art. 110 (3) have applied to all medical devices, even if the manufacturer still holds only EC certification under the EU Directives. Please consider that MEDDEV 2.12-1 is not applicable under MDR/IVDR and take note of the published[3] and upcoming[4] guidances under EU Regulations.

The reporting requirements to TÜV SÜD Product Service GmbH as Notified Body under MDR/IVDR are established in the Testing and Certification Regulations of the TÜV SÜD Group[5] (TCR) and specified in the respective application forms for certification (MDR or IVDR). These documents establish the contractual agreement regarding vigilance reporting between the legal manufacturer and the Notified Body TÜV SÜD Product Service GmbH.

Copies of all vigilance reports referred to in Art. 92 (1) lit. a – c, e MDR/Art. 87 (1) lit. a – c, e IVDR must be sent to TÜV SÜD Product Service GmbH at the same time with your notification to Competent Authorities (CA), including non-reportable final manufacturer incident reports (MIRs).

How to report to TÜV SÜD Product Service GmbH?

The vigilance report must include the names of the manufacturer and the product exactly as given on the EC/EU certificate or the list of CE-marked devices respectively. Please also add the certificate holder's TÜV SÜD client number in the Comments section of the reporting form.

Until EUDAMED is fully functional for vigilance reporting, please send us a separate email for each vigilance report to mhs-vigilance@tuvsud.com. You will receive an automatic confirmation of receipt by email.

Accepted file formats are:

- XML files for MIR and FSCA report
- PDF files for FSCA report, FSN, trend report and periodic summary report

All documents must be in English or German.
Current reporting forms as published by the European Commission must be used.

Additional details on reporting of MIRs

Kindly refer to the guidance "Manufacturer incident report Helptext"[6] provided by the European Commission. Please include the following information in your report: for example, correct IMDRF adverse event reporting terms and codes, results of case-specific risk assessment, root cause / most probable root cause, number of current EC / EU Quality Management System certificate (already in the initial report), Notified Body ID Number (0123) and information on the efforts made to retrieve the concerned device for investigation.

In addition to meeting the reporting deadlines for initial vigilance reports (after date of awareness), follow-up or final reports should be filed according to the specified 'date of next report'.

Additional details on reporting of FSCAs

If a Field Safety Corrective Action (FSCA) is performed in multiple countries, it is sufficient to send us copies of the reports submitted to a single CA (preferably the German Federal Institute for Drugs and Medical Devices "BfArM" or German Federal Institute for Vaccines and Biomedicines "PEI" as applicable). An information you provide to your clients being titled "Field Safety Notice" (FSN), by definition, requires the submission of an FSCA report.

Billable service

Please note that the assessment of vigilance information is a fee-based service. For each assessed vigilance case we thus charge the fee specified in the standard fees of TÜV SÜD Product Service GmbH[7].

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

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[1] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02017R0745-20200424

[2] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02017R0746-20220128

[3] https://ec.europa.eu/health/medical-devices-sector/new-regulations/guidance-mdcg-endorsed-documents-and-other-guidance_en

[4] https://ec.europa.eu/health/document/download/b14e2630-6d0a-4f02-a494-d0a89c48e7a4_en?filename=mdcg_ongoing_guidancedocs_en.pdf

[5] https://www.tuvsud.com/en/terms-and-conditions/group-testing-and-certification-regulation

[6] https://ec.europa.eu/docsroom/documents/37350

[7] https://www.tuvsud.com/en/industries/healthcare-and-medical-devices/medical-devices-and-ivd/medical-device-market-approval-and-certification/medical-device-regulation/mdr-conformity-assessment-procedures

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