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**PROCEDURE FOR VIGILANCE AND ADVERSE EVENT INVESTIGATION AND REPORTING**

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# Purpose, scope, and users

The purpose of this Procedure is to define the process of vigilance and incident investigation, and the minimum requirements for the reporting, investigating, and communicating of adverse events and notification of complaints that meet specified reporting criteria of adverse events used in the Quality Management System (QMS) according to the MDR 2017/745.

This Procedure applies to the process of reporting the events to the Competent Authorities and managing inquiries sent by the Competent Authorities for all the products in the market.

Users of this document are all employees of [organization name] inside the scope of the QMS.

# Reference documents

* ISO 13485:2016 standard, clauses 8.2.3 and 8.3.3
* MDR 2017/745, articles 10, 87, 88, 89, and Annex IX – Chapter I
* IVDR 2017/746
* MEDDEV 2.12/1 rev. 8 Guidance document - Market surveillance - Guidelines on a Medical Devices Vigilance System
* Manufacturer Incident Report (MIR) for Serious Incidents (MDR/IVDR) and Incidents (AIMDD/MDD/IVDD), version 7.2.1
* Additional Guidance Regarding the Vigilance System as outlined in MEDDEV 2.12-1 rev. 8
* [national regulations for vigilance system]

# EU vigilance reporting process

For a medical device used on the EU market, [job title] is responsible for fulfilling the vigilance report …

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