MIS À JOUR LE 23/06/2026

How do you report an incident if you are a manufacturer or distributor of medical devices or non-medical devices covered by Annex XVI ?

Consulter la version française

As part of its post-market surveillance and vigilance activities, the ANSM recommends that manufacturers use the European Medical Device Nomenclature (EMDN). This nomenclature is used for the registration of medical devices in the European database EUDAMED.

Annex XVI of Regulation (EU) 2017/745 (MDR) sets out the list of non-medical products which, due to their characteristics or intended use, are subject to the same requirements as medical devices in order to ensure the safety and health of users.

Manufacturer Incident Report (MIR)

New MIR form - mandatory as from 1st May 2026

Documentation related to this update is available on European Commission's website.

- Manufacturers should notify the ANSM of MIR using the MIR Manufacturer Incident Report (MIR) form.
- Manufacturers should sent MIR (pdf and xml format) by mailbox: materiovigilance@ansm.sante.fr.
- To monitor the registration of MIR, manufacturers have an access via Vigimater to put ANSM’s reference.

Access to Vigimater

Field Safety Corrective Actions (FSCAs)

- Manufacturers should notify the ANSM of FSCA using the FSCA Report Form
- Manufacturers should sent FSCA by mailbox: materiovigilance@ansm.sante.fr

Trend report

- Manufacturers should notify the ANSM of trend report using the Manufacturer’s Trend Report Form.
- Manufacturers should sent Trend Report by mailbox: materiovigilance@ansm.sante.fr.

Periodic Summary Report (PSR)

- Manufacturers should notify the ANSM of Periodic Summary Report using the Manufacturer’s PSR Report Form.
- Manufacturers should sent PSR by mailbox: materiovigilance@ansm.sante.fr.

Documents

Reporting

- Manufacturer Incident Report (MIR) form
- Manufacturer incident report Helptext
- FSCA Report Form
- Field safety notice template
- FSN customer reply
- FSN distributor/importer reply
- Manufacturer’s Trend Report Form
- ANSM requests medical device manufacturers who send out a field safety notice to place upon it the barcode of the involved devices
- Vigilance related of medical device (MD) or in vitro diagnostic medical devices (IVD) : Q&A on reading anomalies of the UDI carrier

Device Specific Vigilance Guidance (DSVG)

The following guidances provide additional informations to manufacturers that can assist them to identify incidents and complaints associated with specific medical device on reporting adverse incidents for different types of medical device:

- MDCG 2024-1 - Device Specific Vigilance Guidance (DSVG) Template
- MDCG 2024-1-1 - DSVG 01 on Cardiac ablation
- MDCG 2024-1-2 - DSVG 02 on Coronary stents
- MDCG 2024-1-3 - DSVG 03 Cardiac Implantable Electronic Devices (CIEDs)
- MDCG 2024-1-4 - DSVG 04 on Breast implants
- MDCG 2024-1-5 - DSVG 05 on Urogynaecological Surgical Mesh Implants used for Pelvic Organ Prolapse repair and Stress Urinary Incontinence
- DSVG 05 : Insulin Infusion Pumps and Integrated meter systems