

# How to declare if you are a manufacturer or distributor of medical devices

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## Post-market surveillance and vigilance

Manufacturers are required to submit vigilance reports to the ANSM for any incidents occurred in France involving medical devices, in accordance with Regulation (EU) 2017/745.

The manufacturer must also take appropriate safety action when required.

Further information about [reporting adverse incidents and corrective actions to ANSM](#) is available for manufacturers of medical devices.

We encourage manufacturers to use European Medical Device Nomenclature (EMDN).

### Manufacturer Incident Report (MIR)

- 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](mailto:materiovigilance@ansm.sante.fr).
- To monitor the registration of MIR, manufacturers have an access via Vigimater to put ANSM's reference.

### **New MIR form - mandatory as from 4 months after the date of the publication of the next update of MIR 7.3.1. PDF and related files**

A new version of MIR 7.3.1 will be applicable.

Documentation related to this update is available on the [European Commission's website](#).

[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](mailto: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](mailto: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](mailto:materiovigilance@ansm.sante.fr).

## Documents

### Reporting

- [Manufacturer Incident Report \(MIR\) form](#)
- [Manufacturer incident report Helptext 2020](#)
- [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](#)