MEDICAL DEVICES IN LUXEMBOURG

On the European level, there are two Regulations on medical devices:

- Regulation (UE) 2017/745 (MDR) on medical devices, applicable from 26th May 2021,
- Regulation (UE) 2017/746 (IVDR) on *in vitro* medical devices, applicable from 26th May 2022.

As the European Database on medical devices EUDAMED is not fully functional yet, some provisions of the Directives 90/385/CEE, 93/42/CEE and 98/79/CE concerning the exchange of information remain applicable and regulated on the national level. The detailed information can be found in the guidance documents adopted by the **MDCG** (Medical Device Coordination Group).

Therefore, some national provisions concerning the registration of the devices, registration of economic operators, and the authorisation of clinical investigations remain applicable.

In this regard, the marketing, importation, advertising, and use of medical devices are regulated at national level by:

- The amended law of 16 January 1990 on medical devices,
    - The amended Grand-Ducal Regulation of 5 February 1993 on active implantable medical devices
    - The amended Grand-Ducal Regulation of 11 August 1996 on medical devices
    - The amended Grand-Ducal Regulation of 24 July 2001 on *in vitro* diagnostic medical devices.

CONFORMITY OF THE MEDICAL DEVICES

Any medical device bearing the CE mark, which indicates that it has undergone conformity assessment, can be placed on the market and put into service. Before placing the device on the market, the manufacturer draws up the declaration of conformity in which he declares that the devices meet the provisions of the standards applicable to them.

Regulation (EU) 2023/607 has introduced extended transitional periods for the conformity of the devices not assessed under the MDR or IVDR. **Regulation 2024/1860** has additionally modified the transition periods for *in vitro* medical devices. For further information, please refer to the following MDCG documents:

Q&A on practical aspects related to the implementation of Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

Q&A on practical aspects related to the implementation of the extended transitional period provided for in the IVDR, as amended by Regulation (EU) 2024/1860 of 13 June 2024 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards a gradual roll-out of Eudamed, the obligation to inform in case of interruption or discontinuation of supply, and transitional provisions for certain in vitro diagnostic medical devices

LANGUAGE REQUIREMENTS

For active implantable medical devices, the instructions to be provided to users and patients must be written in one of the following languages: French or German.
For medical devices and *in vitro* diagnostic medical devices, the information to be provided to users and patients must be written in one of the following languages: French, German or Luxembourgish. If the device is intended exclusively for professional use, this information may also be provided in English.

For more detailed information on language requirements for medical devices in Luxembourg, please visit the following Website of the European Commission:
Overview of language requirements for manufacturers of medical devices - European Commission

REGISTRATION OF AN ECONOMIC OPERATOR

Any manufacturer who places devices on the market under their own name must, if established in Luxembourg, register with the Health Directorate (meddevices@ms.etat.lu).

If a manufacturer does not have a registered place of business in a Member State, he shall designate a single Authorised Representative in the European Union. Any European representative established in Luxembourg must register with the Health Directorate (meddevices@ms.etat.lu).

Economic operators (manufacturers, representatives, importers, systems and procedure packs providers) established in Luxembourg can register themselves via **EUDAMED Actor Registration Module**, in accordance with the Regulations. Each registration application must be validated by the relevant competent authority.

The above-mentioned economic operators are encouraged to register themselves as soon as possible, taking into account the deadlines set out in **Regulation 2024/1860**.

Currently, there is no registration foreseen for distributors in Luxembourg, nevertheless, this may change in the future.

REGISTRATION OF A DEVICE

Before placing a medical device or an in vitro diagnostic medical device on the market, any manufacturer, or his authorised representative, if established in Luxembourg, must register their class I devices or the *in vitro* diagnostic medical device with the Health Directorate. For this purpose, the applicant should send the following documents to meddevices@ms.etat.lu:

- A recent extract from the RCS (not older than 3 months)
- Declaration of Conformity
- Certificate(s) of Conformity, if applicable,
- QMS certificate, if applicable
- IFU (instruction for use)
- Copy of the labelling.
- In certain cases, Technical Documentation may be requested.

For further questions, you may consult meddevices@ms.etat.lu

Regarding medical devices of higher classes, they can be registered directly in **EUDAMED**, once the registration of the relevant economic operators (manufacturer and/or European representative, if applicable) has been validated. The Health Directorate reserves the right to request all relevant documents proving the conformity of the devices concerned.

There is no obligation to notify in Luxembourg the distribution of CE-marked medical devices. In this respect, distributors of medical devices are not required to register with the Health Directorate. However, there are language requirements that must be complied with at national level (see also point **LANGUAGE REQUIREMENTS**).

DEROGATION REQUEST

To apply for a derogation from the conformity assessment procedures for the placing on the market/putting into service of a medical device/in vitro diagnostic medical device on the territory of Luxembourg, pursuant to Article 59 of the MDR or Article 54 of the IVDR, the applicant must send the completed form together with all relevant documents to the following address: meddevices@ms.etat.lu. Only complete applications will be taken into consideration.

- **Fiche de renseignement demande dérogation de procédures conformité CE_v1.2**

CERTIFICATES OF FREE SALE

The Certificate of Free Sale (CFS) is a document certifying that the medical device of a Luxemburgish manufacturer or a European representative established in Luxembourg complies with the applicable legislation and can be commercialized in the European Union (EU).

The CLV is intended for a health authority in an importing country outside the European Union (EU). It is requested by a manufacturer or an authorised representative with a view to exporting a medical device (MD) or an in vitro diagnostic medical device (IVD) outside the EU.

a) **"New devices"** according to the **MDR** or the **IVDR**

The forms should be accompanied by the following documents:

- A recent extract from the RCS (no older than 3 months),
- Declaration of Conformity (DoC),
- Certificate(s) of Conformity (CoC), if applicable,
- QMS certificate, if applicable,
- IFU (Instruction for Use),
- Copy of the labelling,
- In some cases, the Technical Documentation may be requested.

b) **"Legacy devices"** according to Article 120 of the **MDR** or Article 110 of the **IVDR** (see also **Regulation (EU) 2023/607)** and the MDCG Guidelines **Q&A on practical aspects related to the implementation of Regulation (EU) 2023/607**)

The forms should be accompanied by the following documents:

- A recent extract from the RCS (no older than 3 months),
- Declaration of Conformity (DoC),
- Certificate(s) of Conformity (CoC), if applicable,
- IFU (Instruction for Use),
- Copy of the labelling,
- QMS certificate, if applicable,
- Manufacturer's declaration according to Regulation (EU) 2023/607 (MDR) or Manufacturer's Declaration according to Regulation (EU) 2024/1860 (IVDR),
- Copy of written agreement with the Notified Body
- In some cases, the Technical Documentation may be requested.

c) **"Other devices"** (Devices older than legacy devices)

The provision of CFS for this type of devices is currently under legal review. As soon as this process is completed, this page will be updated accordingly.

Applications must be sent to the *Division de la pharmacie et des médicaments* (2a, rue Thomas Edison, L-1445 Strassen) using the following forms, in accordance with the applicable legislation (see below).

The form should be printed out and signed per hand in **N+1** exemplars since one copy will be kept by the Health Directorate. Please note that a CLV form may only include the devices listed on the same DoC and/or the same CoC. The forms should be accompanied by the several documents listed below. Alternatively, copies of these documents can be also sent by e-mail to meddevices@ms.etat.lu. For files larger than 10 MB, please send an email to meddevices@ms.etat.lu with the subject "Submission of CLV request files larger than 10 MB". You will receive an email with an OTX link (One Time Exchange application) to transfer the files.

In case of additional questions, please contact meddevices@ms.etat.lu

APPLICATION FORMS:

- CFS form for devices covered by the MDR
- CFS form for devices covered by the IVDR
- CFS form for devices covered by Article 120 of the MDR (Legacy devices)
- CFS form for devices covered by Article 110 of the IVDR (Legacy devices)

VIGILANCE

All Vigilance reports, including MIR (Manufacturer's Incident Report), FSCA (Field Safety Corrective Action), PSUR (Periodic Safety Update Report), PSR (Periodic Summary Reports) and TR (Trend reports) should be sent to meddevices.vigilance@ms.etat.lu, using the most recent version of the form available on the European Commission website.

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

Regarding the MIR and FSCA forms, we request both pdf and xml formats.

For the FSN, reflecting the linguistic situation of the medical sector in Luxembourg, we suggest at least the French and German versions in addition to the English one. The FSCA notifications should be also accompanied by:

- the list of Luxembourgish users/customers affected by this FSCA,
- An overview of the number of affected products supplied to the Luxembourgish market,
- a confirmation of transmission of the FSN to Luxembourg users/customers.

It is also recommended to consult the **MDCG guidelines**, in particular:

- **MDCG 2023-3** Questions and Answers on vigilance terms and concepts as outlined in the Regulation (EU) 2017/745 on medical devices,
- **MDCG 2024-1** Guidance on the vigilance system for CE-marked devices.

NOTIFICATION OF SERIOUS INCIDENTS BY HEALTHCARE PROFESSIONALS, USERS AND PATIENTS

What is an incident?

Any malfunction or deterioration in the characteristics or performance of a device made available on the market, including use-error due to ergonomic features, as well as any inadequacy in the information supplied by the manufacturer,

- and any undesirable side effects (in the case of medical devices).
- and any harm as a consequence of a medical decision, action taken or not taken on the basis of information or result(s) provided by the device (in the case of in vitro diagnostic medical devices).

What is a serious incident?

Any incident that directly or indirectly led, might have led or might lead to any of the following:

a) the death of a patient, user or other person,
b) the temporary or permanent serious deterioration of a patient's, user's or other person's state of health,
c) a serious public health threat.

How to declare?

The notification of a serious incident should be sent to meddevices.vigilance@ms.etat.lu, by completing the dedicated **Notification form (FR/DE)**. Our **Guide to the form (FR/DE)** will help you complete your declaration. Concerning data protection, please consult the following document **Data protection (FR)**.

CLINICAL INVESTIGATIONS OF MEDICAL DEVICES

For more information regarding clinical investigations of medical devices in Luxembourg, you may consult the following specific websites:

- Investigations cliniques au Luxembourg (FR)
- Clinical investigations in Luxembourg (EN)