



## Application for an operating permit for a class III establishment

to carry out exposures for medical purposes using X-ray generating equipment for use in conventional dentistry (three-dimensional imaging excluded)



The undersigned hereby requests, in compliance with Articles 44 and 49 of the Law of 28 May 2019 on radiation protection, an operating permit for a class III classified establishment for the implementation of the following practices: using X-ray generating equipment to carry out exposures for medical purposes (diagnostic radiology without tridimensional reconstruction techniques).

### 1. Input

Fields marked with an \* are compulsory

#### General information on the applicant

Surname(s) and first name(s) of the applicant\*:

Capacity (e.g. dentist)\* :

Usual place of residence\*:

National identification number\*:

Name of the dental office:

Address of the dental office:

In the case of an application for a company:

Business name\*:

Registered office\*:

Administrative office\*:

#### Purpose of the application and equipment

The present application is:

- ☐ **an initial application**
- ☐ application for **renewal without modification**
- ☐ an application for a **modification** (e.g. X-ray devices, address, etc.)

#### Radiation protection officer

This is the contact person for exchanges between the establishment (dental office) and the Radiation Protection Division. This person must be technically competent in radiation protection matters concerning dental radiology in order to supervise or implement radiation protection provisions. Their tasks are described in Art. 7 of the Grand Ducal regulation on radiation protection. In the event that this position will not be held by the applicant dentist, the following duly trained employee shall be appointed:



Surname and first name\*:

Business address\* :

Business phone number\*:

Business email address\*:

please attach:

- a certificate attesting to the radiation protection qualification of the person responsible for radiation protection and, where appropriate, of his or her substitute representative.

#### External consultant

This is either an expert in radiation protection, an expert in medical physics or a person responsible for radiation protection external to the establishment, in accordance with the provisions of Article 21 paragraph 5 of the law. The person verifies the conformity of radiation sources and installations (Article 53 of the law) and carries out quality controls of the medical imaging chain (Article 102 of the law, serving as a reference for the quality assurance programmes to be implemented by the establishment - Article 101 of the law):

Surname and first name of the consultant:

Business address:

Business phone number:

Business email address:

please attach:

- The sheet for the inventory of X-ray equipment (Form-List-Xray-Equipment-DENT) must be completed and attached to the application for authorisation.
- For new equipment listed in the inventory: Proof of **compliance** with the European regulation on **medical devices** (Regulation (EU) 2017/745): EC marking: **declaration of conformity** and **certificate of the notified body**
- The identifier of the cadastral plot.
- One or more **maps of the radiology installations** and premises indicating for each X-ray device the **position of the patient's head** during their exposure, the position of the **trigger**, the **intended use of adjacent rooms** as well as the **materials** and **thickness of the walls** of the rooms used for radiology procedures.
- For **other dental practitioners** practising or wishing to practise dental diagnostic radiology in the establishment: copies of decrees authorising the practice of dental diagnostic radiology or applications to practice diagnostic radiology in dental medicine.
- A certificate (or at least a draft of a contract) of public liability **insurance** covering the use of ionising radiation sources or **X-ray equipment** and indicating the location of the risk or the territorial extent of the risk.



## 2. Signature

The undersigned declares that the data provided is correct and truthful.

The undersigned declares:

- to be responsible for the radiological equipment (safety, use, quality assurance, ...)
- that he or she is aware that it is forbidden to delegate the taking of radiographs to persons who do not have ministerial authorisation to do so
- before commissioning, each X-ray device must be approved and tested.
- having taken note that by the deadline of 1 June of the year, all Class III establishments are required to pay a fee of EUR 200 and that proof of payment is to be sent to the Health Directorate

Done at\*:

Date\* :

### Head of the establishment

Surname and first name(s)\*:

Signature\*:

### Radiation protection officer

(if different from the head of the establishment)

Surname and first name(s)\*:

Signature\*: