

Ref: Declaration of turnover for the year 2023, in accordance with Articles 14/2 to 14/6 of the Law of 20 July 2006 - Law on the Establishment and Operation of the Federal Agency for Medicines and health products.

I, undersigned, _____, as accountant or auditor, certify and declare that this declaration is true and accurate.

Part 1: Identification of the enterprise:

Name and legal form:

Registered address or head office and, if different, place of business:

Company number:

FAMHP notification number:

Part 2: Total annual sales of medical devices:

This turnover is not taxable.

I declare that my total annual turnover related to medical devices in Belgium is less than EUR 48,798.42 excluding VAT.

I declare that my total annual turnover related to medical devices in Belgium exceeds EUR 48,798.42 excluding VAT.

Please provide the total annual turnover excluding VAT for medical devices in Belgium:

Please also complete the next page.

Part 3: Annual turnover related to the sale and supply of medical devices to retailers and end users:

The contribution will be calculated based on this declared amount and is equal to a maximum of 0.2868% of it.

End user: Any natural or legal person, other than a distributor, who uses a medical device within the framework of his professional activities (i.e.: healthcare institutions, doctor, dentist...).

retailer: any natural person or legal person who supplies devices to consumers (consumer: any natural person who weaves or uses devices exclusively for non-professional purposes).

As liable party¹, I declare that my annual turnover related to the sale and delivery of medical devices to an retailers and end users on Belgian territory² is less than EUR 48,798.42 excluding VAT.

As liable party¹, I declare that my annual turnover related to the sale and delivery of medical devices to an retailers and end users on Belgian territory² exceeds EUR 48,798.42 excluding VAT.
Please provide the annual turnover excluding VAT related to the sale and delivery of medical devices to retailers and end users on Belgian territory²:

Done and signed in:

Date:
(dd-mm-yyyy)

Signature:

¹: **Liable:** The actors that make available of medical devices to retailers and/or end users, in accordance with article 14/2 and annex I.1 of the aforementioned law of 20 July 2006. An end user is defined by article 2, § 1, 20° of the aforementioned law of 20 July 2006 as « any natural or legal person, other than a distributor, who uses a medical device in the context of his professional activities ». Retailers, as defined in article 2, § 1, 19° of the aforementioned law of 20 July 2006, remain exempted from this tax. A retailer is defined as: « any natural or legal person who supplies devices to consumers, namely any natural person who acquires or uses devices exclusively for non-professional purposes ». For actors who carry out retail activities, but also supply medical devices to retailers and/or end users, the latter activities remain subject to tax. Only their retail activities are exempt. 2: In overeenstemming met artikel 14/2 en bijlage I.1 van de wet van 20 juli 2006 betreffende de oprichting en de werking van het FAGG.

²**Foreign companies:** the contribution is due for actors located abroad carrying out at least one activity subject to contribution on Belgian territory. You must communicate the turnover concerning the making available of medical devices to retailers and/or end users on the Belgian territory.

Declaration - v. 12-03-2024