

To whom it may concern

Subject: MDD certificate expiration

The Medical Device Directive 93/42/EEC (MDD) has been replaced by Regulation (EU) 2017/745 (MDR), in force since 26/05/2021, which provides for a transition period from MDD Directive to MDR Regulation through the Art. 120.

Flaem Nuova S.p.A. obtained the MDR certificate from its Notified Body on January 30th, 2023 in relation to the following product categories:

- Aerosoltherapy equipment
- Ultrasonic aerosoltherapy equipment
- Accessories for aerosol therapy
- Nasal wash
- Suction equipment
- Accessories for suction equipment

The natural expiry date of the certificate 672/MDD of Flaem Nuova S.p.A. is set on April 11th, 2023; therefore from that date the production of the devices covered by this certificate should stop.

However, Regulation (EU) 2023/607 of the European Parliament and of the Council of March 15th, 2023 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards transitional provisions for certain medical devices and in vitro diagnostics medical devices modified the application of the Art. 120 and allows to extend the validity of the CE certificate in MDD beyond the expiry date indicated on the same, provided that certain requirements are met.

Within the EU market, thanks to Reg. (EU) 2023/607, Flaem Nuova S.p.A. will be able to continue the marketing and placing on the market of Medical Devices certified in MDD, and translated into MDR, until **December 31st, 2028**.

For **Extra-EU countries**, on the other hand, the possibility of applying the extension referred to in Reg. (EU) 2023/607 is **strictly bound to the transposition** or otherwise of the same **by the individual States**:

If the Extra-EU country DOES NOT ACCEPT the extension (EU) 2023/607:

In this case, in order to be able to affix the CE0051 marking to its devices, from April 11th, 2023 Flaem MUST absolutely adapt the product to the requirements of the European regulation (EU) 2017/745 (MDR).

The changes that the finished devices will undergo will be on the whole labeling plan (box, user manual, labels affixed to the product).

Distributors/Customers who applied for a Registration to import devices must take immediate action to understand with their Ministry/Agency if the registration should be updated.

The Customer/Distributor is required to issue a letter of indemnity which frees Flaem Nuova S.p.A. from any liability deriving from the failure or incomplete updating of the registration relating to the imported products.

This indemnity must also free the Manufacturer from any liability relating to the importation of products by the Customer/Distributor during the transitional phase of registration's update.



If the Extra-EU country ACCEPTS the extension (EU) 2023/607:

In this case, Flaem Nuova S.p.A. requires a letter from the Customer/Distributor in which is provided authorization to the production and marking of the devices according to MDD after April 11th, 2023 by virtue of the aforementioned extension.

This letter must also indemnify the Manufacturer from any liability deriving from the incorrect interpretation of the acceptance of the extension or from any failure to update the existing registration by the Customer/Distributor.

San Martino della Battaglia (BS), March 29th, 2023

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