Central Administration of Medical Devices
General Administration of Registration of Medical Devices

Notice to Applicant

The mechanism for dealing with the changes mentioned in the MDD certificates extension letters issued by the Notified Body under MDR application in the event that they are not mentioned in the Registration License of the medical device.

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Changes mentioned in the MDD certificates extension letters issued by the Notified Body under MDR application and not mentioned in the registration license of the medical device are divided into 3 groups as follows:

A- Cases that require submission of variation application before or immediately after the change occur:

1- Change of the name and/or address of the legal manufacturer
2- Add/change codes/cancel codes
3- Changing the name of the manufacturer while keeping the same address
4- Changing the address of the legal manufacturer
5- Changing or adding a legal manufacturer
6- Description of the medical device

- The aforementioned changes are proven in the (Free sale & DOC) certificates, and the extension letter issued by Notified Body.
- Regarding the documents required to be submitted for each rule, the regulatory guideline for the procedures and rules organizing the changes done to a registration license data of a medical device is followed.

If the company is unable to obtain a Free sale certificate with the changes, the file will be accepted in reception provided that the company submits the following:

1- A letter from the legal manufacturer stating that the procedures for renewing the Free sale certificate are being carried out within a specified period.
2- Applicant commitment to submit the renewed Free sale certificate within the period specified in the legal manufacturer's letter. This certificate must be submitted before the completion of the variation file.

B- <u>Cases that require applying for the change once the CE certificates in accordance with MDR Regulation (EU) 745/2017 are issued:</u>

1- Upper or down classification in accordance with MDR Regulation (EU) 745/2017
2- Substitute MDR device ((significant) changes with regard to its design or intended purpose)

C- <u>Cases that shouldn't be submitted to the Administration of Medical devices variations:</u>

In the event of changing the trade name of a registered medical device, an application for new-registration shall be submitted, and it is not authorized to market the medical device before the issuance of the new-registration license.