

Notice to applicant Regarding the Registration of Medical Devices with Differences in Composition Data within a Unified Technical Registration File, while Maintaining the Same Intended Use, Medical Purpose, Classification, and Basic Design

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1- Introduction

In the framework of facilitating regulatory procedures and reducing the administrative and technical burden on both service recipients and the competent departments, it has been decided to allow cases in which the composition data of the same medical device differs, to be included within a unified technical registration file while maintaining the same intended use, medical purpose, classification, and basic design of the medical device for cases that meet the conditions and controls specified in this notice.

2- Scope of Application

This procedure applies to cases where the difference in the **composition data** results from variations in the raw materials and/or models of the medical device, subject to the following conditions:

- The intended purpose and medical use of the devices remain unchanged.
- The classification remains unchanged.
- The basic design of the device and its medical purpose remain unchanged.
- All codes and/or models requested to be included shall be clearly identified within the technical file, with the differences in composition for each clearly stated.

This procedure does not apply to medical devices that are already registered and shall apply to new registration applications in accordance with the controls set forth in this notice.

3- Fees and Service Charges

The **prescribed fees and service charges** shall be collected for each item/code and/or model included in the file, pursuant to **separate receipts for each item**, in accordance with the applicable financial rules.

4- Issuance of the Registration Notification

Only one **Registration License** shall be issued for each **unified technical file** that meets the requirements, provided that the license includes a detailed statement of all codes and/or models included in the file.

The registration license shall also include, as applicable, a statement of the differences in the **composition data** between the codes and/or models included in the file.