**TECHNICAL SUMMARY**

1. **Trade name or commercial name**

*Brand or medical device commercial name –as desired in the Mexican registration.*

1. **Generic Name**

*Generic name.*

1. **Medical device description**

*Medical device description that matches the technical information from the manufacturer (e.g. IFU or commercial brochures).*

*Include images, photo, diagrams, graphics and any visual tool that make the product understandable.*

* 1. **Indications for use**

*Include indications for use that matches the IFU (Instructions for use) or user manual.*

* 1. **Contraindications**

*Include contraindications for use that matches the IFU, user manual or risk management documentation.*

* 1. **Cautions**

*Include cautions for use that matches the IFU or user manual.*

* 1. **Operation Principle**

*Include the operation principle, if applicable.*

1. **Composition, description or diagram of product functional parts**

*Include a detailed description of the device, highlighting parts names, views, components, accessories, Quali-Quantitative formula, as applicable.*

*Include sub-chapters for every component, if applicable.*

*Pictures and visual tools are also acceptable.*

1. **Finished Product Specifications**

*Include finished product specifications that matches the certificate of analysis and other tests to the product before it is released.*

*Include sub-chapters for every component, if applicable.*

1. **Manufacturing Process**

*Include a brief description of the manufacturing process, either with a summary or through descriptive flow charts.*

* 1. **Manufacturing site**

*Include the name of the manufacturing site or sites, as applicable.*

*The legal documentation must support this information.*

1. **Sterilization**

*In this section declare the sterilization method and the level of sterility assurance (SAL).*

* 1. **Sterilization method**

*Present a summary of the sterilization process, reports and certificates of sterility.*

* *Type of sterilization process*
* *Validation summary*
* *In case of sterilization by ethylene oxide, the results of the ETO residue test must be presented*

1. **Stability or Shelf life Studies**

**Period shelf life established:**

*Expiration date must be stated for each product presentation applicable to this registration.*

**Summary and Conclusions of the Stability Study:**

*Abstract must contain (when applicable):*

* *Name of the medical device*
* *Presentations*
* *No. of evaluated batches*
* *Batch size*
* *Packaging composition*
* *Terms of study*
* *Test parameters*
* *Criteria of acceptance and reference to the methods of analysis*
* *Sampling and analysis times, with analytical results by storage condition and dates of analysis*
* *Evaluation of data and conclusions*

*Stability studies can be under accelerated aging (as long as it is conclusive, it has the scientific support and contains the summary of the protocol, reports, statistical data, results and conclusions) or in real time aging.*

1. **Summary of toxicity or biocompatibility tests**

*Present a summary of the biocompatibility tests (if applicable) that includes at least:*

* *Material to be tested (those in direct contact with the body)*
* *Name of the test*
* *Date of testing*
* *Summary of the test*
* *Results*
* *Conclusion*

*Including a table that summarizes the (e.g.) NAMSA reports, is well accepted.*

1. **Primary and secondary packaging description**

*Present a summary of the packaging of the medical device that preserves the sterility/stability conditions, when applicable.*

*Declare the packaging: material, type, size and any other information that helps to understand how the device is packaged.*

*Pictures and visual tools are well accepted.*

1. **Components**

*Present a list of all the codes included in the registration, using a similar table as below:*

|  |  |  |
| --- | --- | --- |
| ***Identifier or product code*** | ***Name as per Device Label*** | ***Brief Description of Item*** |
|  |  |  |
|  |  |  |

*The legal documentation must support this information.*

1. **Clinical data/studies**

*Publications of the studies for equivalent or similar products. And if necessary, present preclinical studies.*

1. **Documental references**

*Include a list of scientific articles, journal, e-publications or other documents that refer to the medical device to be registered or significantly equivalent devices.*

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*Signature*

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*Name and position*

*Manufacturer’s Responsible Person*

*[Company name]*