Health Permit/ Renewal – Colombia

Medical Devices and Biomedical Equipment (Classes I, IIa, IIb and III)

General requirements for health permit registration

1 Legal requirements

- Power of attorney on behalf of SPI - apostilled / legalized
- Free sales certificate / CFG / CPP (as applicable) - apostilled / legalized
- GMP/ ISO (as applicable) - apostilled / legalized
- Letter of authorization to the importer (LOA)
- Trademark registration (recommended)
- Local requirements for importers

2 Technical Information

- Technical data sheet / Product description / qualitative-quantitative composition
- Support studies (Biocompatibility, electrical safety, shelf life, claims, clinical, risk analysis) as applicable
- IFU / User Manual / Indications
- Label artwork
- COA (Certificate of analysis)
- Commercial history (including health alerts report)

These are general requirements. Once we advance in the process a list of requirements will be informed in detail according to the type of product and classification

Key considerations for regulatory compliance

- **Risk Classification:** Authorities may reclassify products regardless of their original classification.
- **Legal Paperwork:** Must be legalized/apostilled and officially translated.
- **Technical Documents:** Requires local language translation (summaries are sometimes sufficient).
- **Registration holder:** For Colombia, foreign companies may be the holder for the registrations.