Medical Devices Product License Requirements

1. Production Certificate
2. Distribution Certificate
3. Letter of Authorization*
4. Certificate of Conformity
5. Executive Summary
6. Standards and Evidence of Standard Conformity
7. Trademark Patent Statement / Releasing Agency
8. Statement of Data Authenticity

1. Product Description
2. Description and Features of Medical Devices
3. The intended use
4. Indication
5. Instructions for use
6. Material and information of origin (local / import)
7. Production Process
8. Flowchart + QC Process

1. Finished product specifications
2. Additional information on product characteristics
3. Sterile process validation (if product is sterile)
4. Specifications and raw material requirements
5. Packaging specifications
6. Analysis Test Results : Clinical Trial Results, CoA finished products, and QC documents

1. Marking Plate /Packaging Design
2. Explanation of the marking plate /packaging design
3. IFU (English and Indonesian)
4. Production Code
5. List of Accessories
6. Other Supporting data

1. Complaint and Recall Handling Procedures and Forms