Legal Requirements for Application for the Notification of Medical Devices under Class A and Registration of Medical Devices under Classes B, C and D

1. Notarized Application Form
2. Payment
3. Copy of Letter of Authorization. For imported medical devices, the copy of the Letter of Authorization shall be accompanied by an original copy of a notarized declaration from the legal manufacturer or product owner attesting that the authorization is true and correct.
4. A government – issued certificate attesting to the status of the Manufacturer with regard to the competence and reliability of the personnel and facilities, a Quality Systems Certificate of approval, or a compliance certificate for ISO 13485. For imported medical devices, the copy of the certificate shall be accompanied by an original copy of a notarized declaration from the legal manufacturer or product owner attesting that the certificate is true and correct.
5. For imported medical devices, the Certificate of Product Notification, Certificate of Product Registration, or any equivalent document attesting to the safety and effectiveness of the device issued by the regulatory agency or accredited notified body in the country of origin. The copy of the certificate shall be accompanied by an original copy of a notarized declaration from the legal manufacturer or product owner attesting that the certificate is true and correct.
6. Colored picture of the device from all sides. However, the CDRRHR can require a representative sample or commercial presentation for verification purposes.