Requirements for the Renewal of Notification/Registration of Medical Devices for All Classifications

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. Colored picture of the device from all sides. However, the CDRRHR can require a representative sample or commercial presentation for verification purposes.
6. Clear and complete colored pictures of commercial label from all sides of the packaging.