



REQUIREMENTS FOR CHANGING MEDICAL DEVICES

1	Specifications of the Medical Device Subject to Change
2	Previous Registration Number (NIE)
3	Copy of POA (Power of Attorney) / LOA (Letter of Authorization) as sole agent or sole distributor/ distributor who has authorization from principle/ manufacturer to register the medical device at Ministry of Health which legalized by KBRI (ID embassy in country of principle/ manufacturer). POA needs to listed product codes.
4	Give the Certificate of Free Sale from authorized institutions
5	Previous Label Design
6	Revised Label Design
7	Medical Device Distribution License (IDAK)
8	Good Distribution Practice Certificate for Medical Devices (CDAKB)
9	Intellectual Property Rights (IPR) Certificate for Trademark
10	Instructions for Use (IFU) in Bahasa Indonesia and English
11	Accessories File

