

ANNEX C
(normative)

Medical Device Safety and Performance Declaration Template

[To be printed on Manufacturer's Letterhead of the registration holder]

Chief Executive
Medical Device Authority
Level 6, Prima 9, Prima Avenue II
Block 3547, Persiaran APEC,
63000 Cyberjaya Selangor,
Malaysia

[Date]

Dear Sir/Madam,

Declaration of Medical Device Safety and Performance on Change Notification

I, on behalf of *[company name]*, the manufacturer of the medical device(s) stated below, hereby declare that the medical device(s) in this change notification,

- conform(s) to the Essential Principles for Safety and Performance as per the statutory requirements of the Medical Device Act 2012 (Act 737) and the Medical Device Regulations 2012.
- conform(s) to the Post Market requirements as per The Medical Devices (Duties and Obligations of Establishments) Regulations 2019.

This declaration shall apply to the following medical device(s):

[List containing medical devices names and registration submission ID]

I am aware that a false declaration is an offence under Section 76 of Act 737 and may result in the cancellation of registration of the above medical devices under Section 5 of Act 737.

Yours Faithfully,

[Signature]

[Full Name and Title (Top Management Official)]

[Company stamp]