

(EXAMPLE)

DECLARATION OF CONFORMITY

[To be printed on Company Letterhead of Product Owner or Physical Manufacturer]
We, *[name of Product Owner or Physical Manufacturer]*, as the *[Product Owner or Physical Manufacturer]*, hereby declare that the below mentioned devices have been classified according to the classification rules and conform to the Essential Principles for Safety and Performance as laid out in the Medical Device Regulations in Thailand according to the Medical Device Act B.E. 2551 (2008) and the amended Medical Device Act B.E. 2562 (2019), 2nd edition.

Name and Address of Product Owner:

< Product Owner who is responsible for medical device according to the definition of ASEAN Agreement on Medical Device Directive >

Name and Address of Physical Manufacturer:

< Physical Manufacturer who performs the activity of manufacture >

Name and Address of Authorized Representative:

< Local authorized representative responsible for placing the medical device on the market of Thailand >

Medical Device(s):

< e.g. product name and model number >

Risk Classification: e.g. Class 2, rule 11

< Class of Device according to the classification rule, and the rule used to determine the classification >

Quality Management System Certificate: (for Physical Manufacturer)

< ISO, Certification Body and Certificate Number, issue date, expiry date >

Standards Applied: (for Medical Devices)

< International standards; OR Regional Standard; OR See Attached Schedule for multiple standards >

This declaration of conformity is valid from <Day Month Year >

Authorized Signatory:

Name, Position

Date