# DECLARATION OF CONFORMITY

*[To be printed on Company Letterhead of Product Owner]*

Name and Address of Product Owner:
*< Person responsible for manufacturing the medical device>*

We 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 Health Products (Medical Devices) Regulations.

Medical Device(s):
*< e.g. product name and model number>*

Manufacturing Site:
*< Person responsible for manufacturing the medical device>*

Risk Classification: e.g. Class B, rule 6 / Class A, rule 1
*< Class of Device according to the classification rule, and the rule used to determine the classification>*

Quality Management System Certificate:
*< Certification Body and Certificate Number, issue date, expiry date>*

*For Class B, Class C and Class D medical devices, declaration of conformity to either of the following QMS standards is mandatory:-*

- *ISO 13485*
- *US FDA Quality System Regulations*
- *Japan MHLW Ordinance 169*

*For Class A medical devices that are not manufactured under either of the abovementioned QMS standards, certification obtained for alternative QMS standards (e.g. ISO 9001) shall be listed in this section, if applicable.*

Standards Applied:
*< International standards; OR Regional Standard; OR See Attached Schedule for multiple standards >*

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

Authorised Signatory:

_____ _____

Name, Position Date