DECLARATION OF CONFORMITY

[To be printed on Company Letterhead of Product Owner]

Name and Address of Product Owner:

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.

Manufacturing Site:

< Physical manufacturing site(s) including sterilization site(s) >

Medical Device(s):

< e.g. product name and model number>

Risk Classification: e.g. Class B, rule

< Risk Classification of medical device(s) according to the classification rule, and the rule(s) used to determine the classification>

Quality Management System Certificate:

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

NOTE *Declaration of conformity to a quality management system standard is not mandatory for manufacturers of* ***Class A non-sterile*** *medical devices. Quality management system requirements for* ***Class A sterile*** *medical devices can be found in GN-15, Guidance on Medical Device Product Registration.*

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