Declaration of Conformity Template

Name and Address of Manufacturer
[please print on Company Letterhead of Manufacturer]

DECLARATION OF CONFORMITY
I, < please provide the name of person responsible for manufacturing the medical device>, hereby declare that the below mentioned medical device—

(i) complies with all the requirements under the Act;

(ii) has been classified according to the classification rules as specified in First Schedule on Rules of Classification of Medical Device; and

(iii) conforms to requirements specified in APPENDIX 1 of Third Schedule on Essential Principles for Safety and Performance of Medical Devices under Medical Devices Regulations 2012.

(A) Particulars of medical device

Generic name:

Specified name:

Brand/model:

Manufacturer:

Country of origin:

Manufacturing site:

Risk-based classification:

Classification rule:

(Note: according to First Schedule on Rules of Classification of Medical Device)

GMDN code:

Medical device registration number or any approval code:
(B) Quality Management System certificate ("QMS")
Conformity Assessment Body issuing the certificate:

Certificate number:
Issuance date:
Expiry date:
Note:

(i) For Class B, Class C and Class D medical devices, declaration of conformity to either of the following QMS standards is mandatory:
   (a) MS ISO 13485; or
   (b) Other quality management system standard recognised by the Medical Device Authority.

(ii) For Class A medical devices that are not manufactured under either of the above mentioned quality management system standards, certification obtained for alternative quality management system standards shall be listed in this section, if applicable.

(iii) For Class A medical devices with measuring function, conformity assessment certificate and calibration and metrology report, issue date, expiry date, calibration should be provided.

(iv) For Class A medical devices with sterilization, validation report and conformity assessment certificate number, issue date, expiry date should be provided.

(C) Standards Applied
Please state and list all standards applicable for the above-mentioned medical device.
I am fully responsible with all the information provided in this declaration. This declaration of conformity is valid from ............... (Day) ................. (Month) .................. (Year).

I fully understand and acknowledge that it is an offence under Section 76 of the Medical Device Act 2012 [Act 737] to make, sign or furnish any declaration, certificate or other document which is untrue, inaccurate or misleading.

Authorised Signatory:

____________________ _______________
Name:

____________________ _______________
Position:

____________________ _______________
Date:

Note: The Declaration of Conformity, all document and certificates and attestations shall be duly certified true copy by the Applicant.