### ANNEX 5

*[To be printed on company letterhead]*

**Declaration of Conformity to a Quality Management System (QMS)**

Dear Sir/Madam

I hereby attest that *[Company name]* **manufactures, imports and/ or wholesales**\* only medical devices classified as Class A under the Health Products (Medical Devices) Regulations 2010.

The **manufacture, import and/ or wholesale**\* of the Class A medical devices is carried out by *[Company Name]* at the following location(s):

|  |  |  |
| --- | --- | --- |
| **No.** | **Activity** |  **Address of company** |
| 1 | Manufacture/ Import/ Wholesale  |  |

*[Company name]* has established a QMS in accordance with the requirements of *[ISO 13485 / GDPMDS\*]* for the **manufacture, import and/or wholesale\*** of Class A medical devices at the above stated locations*. [Company name]* will continuously monitor, control and maintain the QMS processes to ensure conformity to *[ISO 13485 / GDPMDS\*]* throughout the life cycle of the Class A medical devices.

This declaration is for the purpose of my application(s) for **manufacturer’s, importer’s and/ or wholesaler’s\* licence(s)**. I am informed and I understand that the licence(s) may be suspended or revoked if there are reasonable grounds to believe that:

* the company is in breach of the above attestation;
* the issuance of the licence has been obtained by fraud or misrepresentation by my company;
* the licensee has contravened or is contravening any provision of the Act and Regulations relating to medical devices, any condition attached to the licence or any other prescribed requirement;
* the licensee no longer satisfies any of the prescribed requirements based on which the licence was issued; or
* it is in the public interest to do so.

I am informed and understand that:

* the company shall adhere to storage conditions of the medical device as stipulated by the product owner
* the company shall adhere to transportation conditions of the medical device as stipulated by the product owner
* the company has to maintain records of import and supply
* the company has to maintain records of complaints
* the company has to report defects and adverse effects to HSA
* the company has to notify HSA concerning product recalls; and
* there is prohibition against false or misleading advertisement of the medical device which the company markets.

I am informed and I understand that it is a contravention of Section 24(6) of the Health Products Act to make any statement or furnish any document which I know to be false or misleading.

*\*Delete as appropriate*

Name and Address of Company

Name & Designation

Signature and Date