### ANNEX 1

*[To be printed on company letterhead]*

**Declaration for Exemption from GDPMDS Certification**

I hereby attest that \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, qualifies to be exempted from

 Company name

GDPMDS certification for the purpose of my application(s) for **\* importer’s / wholesaler’s** licence(s) (\*delete accordingly).

The activities for exemption are:

**Activity 1**: Dealing with medical devices that are solely for export or re-export. The medical device will not be supplied in Singapore; or

**Activity 2**: Dealing with medical devices for non-clinical use. The medical device will not be used on any patient.

I further declare that the activity of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_,
 Company name

is **\* Activity 1 and/or Activity 2** (\*delete accordingly).

I am informed and I understand that the above 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.

Name and Address of Company

Signature and Date

Name & Designation