**ANNEX 1**

*[To be printed on dealer Letterhead]*

**Declaration on FSCA Completion**

We, *[name of dealer]*, hereby declare that the list of consignees in Singapore supplied with medical device affected by FSCA *[HSA FSCA Ref No.]*, are limited to:

|  |  |  |
| --- | --- | --- |
| **Consignee Name**  *(For FSCA involving implantable devices, provide qualified practitioner name and relevant healthcare institution in each row)* | **Quantity** | **Status of field safety correction action for affected device**  *(Provide reason if incomplete)* |
| *[Provide consignee full name e.g. clinic or hospital]* |  | *[e.g. completed]* |
|  |  |  |

For all affected consignees whose status of FSCA is listed as completed in paragraph 1:

1. We confirm that we have provided a copy of the Field Safety Notice (FSN)/ Dear Healthcare Professional Letter (DHCPL) and have completed all correction activities for the aforementioned FSCA.

2. We confirm that:

FSN/ DHCPLs have been disseminated to affected Healthcare Professionals (HCPs). Completed FSN/ DHCPL acknowledgements have been obtained from all impacted HCPs.

*(Select only if FSN/ DHCPL is required to be disseminated to HCPs.)*

3. Following evidence confirming completion of field corrections for the affected devices has been collected (if applicable).

Service reports for all corrected devices.

*(Applicable for devices which require repair/ correction)*

Completed FSN acknowledgements confirming affected devices will be disposed of as per product owner’s instruction.

*(Applicable for recalls where consignees are instructed to dispose of affected device.)*

Destruction certificates or airway/shipment bill for all recalled devices.

*(Applicable for recalls where affected devices are to be retrieved from consignees.)*

4. All records will be provided to HSA upon request.

5. We attest the information submitted as part of this declaration has been verified to be true and accurate, and are aware of the penalties that apply under the Health Products Act and its subsidiary legislation for false or misleading submissions.

Yours Sincerely,

*[Signature and Date]*

*[Full Name and Title]*

*[Name and address of company]*