**Annex 1**

**“Dear Healthcare Professional” Letter Format**

 *[To be printed on dealer’s letterhead]*

*[Date]*

Dear Healthcare Professional,

cc: Chairman Medical Board and relevant Head of Departments

***[Subject Matter of the Letter]***

*[Dealer’s name]* is issuing the letter to inform…

 *Include:*

* *Introduction of safety update or device problem (e.g. device malfunction or failure)*
* *Concise description of affected device name, model/lot/batch/serial number identified*

**Background/Description of Problem**

 *Include:*

* *Brief product description or device intended use*
* *Factual statement explaining the reason of FSCA, including description of safety update or device problem*
* *Description of hazard and health risk associated to the device problem, where appropriate include, the severity and likelihood of the problem*

**Advisory to Healthcare Professionals**

Healthcare professionals are advised to do the following:

 *Include patient management advice and/or recommended actions to be taken to manage patients previously implanted or to be implanted with the affected device*

**Reporting of Adverse Event**

The Health Sciences Authority has been notified of this issue. Healthcare professionals are advised to report any adverse events and/or suspected adverse reactions associated with these devices to *[dealer contact person’s name and contact information].* Alternatively, healthcare professionals may report the adverse events to the Medical Devices Cluster, Health Products Regulation Group, HSA at Tel: 6866 1048, or report online at [www.hsa.gov.sg/adverse-events](file:///C%3A%5C%5CUsers%5C%5Chsa-xufu%5C%5CDocuments%5C%5CRS_Work%5C%5C18_MD%20GNs%5C%5C05_Active%20Doc%5C%5CGNs%5C%5CGN-09%5C%5CR3.6%5C%5Cwww.hsa.gov.sg%5C%5Cadverse-events). Events that are reported to *[dealer’s name]* will be investigated and subsequently reported to HSA.

Yours Sincerely,

*[Signature]*

*[Full name & Title]*

*[Name and address of company]*

**Possible Attachments:**

1. Photography image of affected device or device defect
2. FAQs
3. Acknowledgement receipts of DHCPL
4. Recall forms

