**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:\\Users\\hsa-xufu\\Documents\\RS_Work\\18_MD%20GNs\\05_Active%20Doc\\GNs\\GN-09\\R3.6\\www.hsa.gov.sg\\adverse-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

