ANNEX B
(informative)

Summary Table of Changes

This annex provides guidelines on completing the Summary Table of Change Notification.

(a) This summary table is to be completed and submitted for all change applications.

(b) List the proposed changes, according to the "category of change", to the registered medical device(s) in the summary table below. All applicable types of changes are to be included; any change not specified in this table will not be included for the change notification.

(c) Information to be included in the table is explained below:

i) **Type of changes:** Please state clearly the **type of change**, **category of change** and **MeDC@St medical device registration number.**

- With reference to the 'type of changes' categories in Table 1, highlight the type of change proposed.
- Specify the MeDC@St medical device registration number for the registered medical device(s) included in this change (if the proposed change is identical and applicable to identical medical devices across multiple device registrations on the MeDC@St; list the applicable medical device registrations). Confirm these medical device(s) subjected to the change.

NOTE *All applicable types of changes are to be included. If the types of change proposed affects/results in another type of change, all types of changes shall be included. For example, change in material of medical device and change (update) of labelling often occur together.*

ii) **Present:** Please state clearly the current scope and aspects of the medical device to be changed.

iii) **Proposed:** Please state clearly the proposed scope and aspects of change.

iv) **Reason for change:** Please state clearly the rationale for the proposed scope and aspects of change.

v) **Status of proposed change in recognised countries:** Please state the reference agency status (approved/authorised for marketing) for these proposed changes.

(a) Type of changes	(b) Present	(c) Proposed	(d) Reason for change	(e) Status of proposed change in recognised countries
Type of change: *e.g. Change in material: Delivery tube material changed from polyvinyl chloride (PVC) to silicone* **Category of change:**	*Delivery tube material: polyvinylchloride (PVC)* **Registration no:** **List of medical device and identifier** i) ii) iii)	*Delivery tube material: silicone*	*Improve patient safety by changing to DEHP-free tubing material*	*Australia TGA – pending* *EU Notified Body – approved/authorised for marketing* *Health Canada – not supplied* *US FDA – not supplied* *Japan MHLW – not supplied*
Type of change: *e.g. Change in manufacturing facility* **Category of change:**	*Name and address of current manufacturing facility A* **Registration no:** **List of medical device and identifier** i) ii) iii)	*Name and address of new manufacturing facility B*	*Reason for to move manufacturing activities from facility A to facility B*	*Australia TGA – pending* *EU Notified Body – approved/authorised for marketing* *Health Canada – not supplied* *US FDA – not supplied* *Japan MHLW – not supplied*