醫療儀器規管架構建議
Proposed Framework on Statutory Control of Medical Devices
(問卷 Questionnaire)

請於 2010 年 9 月 30 日前將這問卷交回「醫療儀器管制辦公室」 (傳真: 3157 1286; 電郵: mdco@dh.gov.hk; 地址: 香港灣仔皇后大道東 183 號合和中心 31 樓 3101 室)

Please return this questionnaire to the Medical Device Control Office by 30 September 2010 (Fax: 3157 1286; Email: mdco@dh.gov.hk; Address: Rm. 3101, 31/F., Hopewell Centre, 183 Queen's Road East, Wanchai, Hong Kong)

姓名 Name : _____

機構名稱 Organisation: _____

業務性質 Nature of business:
(可選擇多於一項)
(can tick more than one box)

- ☐ 本地負責人 /代理人 Local Responsible Person / Agent
- ☐ 進口商 / 出口商 importer/exporter
- ☐ 分銷商 / 批發商 distributor / wholesaler
- ☐ 零售商 retailer
- ☐ 本地製造商 local manufacturer
- ☐ 其他 (請說明) others (please specify): _____

地址 Address: _____

電話號碼 Tel No: _____

傳真號碼 Fax No: _____

電郵地址 Email: _____

請在適當的方格內劃上✔號，以表達對下述說法的意見。

Please indicate your view on the following statements by ticking the appropriate box.

		同意 Agree	不同意 Disagree	無意見 No Comment
1.	政府應立法對醫療儀器進行監管，以確保公眾安全。 The government should regulate medical devices to ensure public safety through legislation.	□	□	□
2.	我/本機構知道政府正推行一套醫療儀器行政管理制度。 I am/My organization is aware that the government is implementing a Medical Device Administrative Control System (MDACS).	□	□	□

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		同意 Agree	不同意 Disagree	無意見 No Comment
3.	大體而言，政府建議的規管架構可以接受。 In general, the regulatory framework proposed by the government is acceptable.	□	□	□
4.	在將來的法規中，「授權代表」將會取代在現有醫療儀器行政管理制度下的「本地負責人」。 The term “Authorized Representatives” is used in the future legislation to replace the term “Local Responsible Persons” under the MDACS.	□	□	□
5.	分銷商必須向衞生署註冊,及遵守一套註冊條件。 Distributors are required to register with the Department of Health and to comply with a set of conditions for registration	□	□	□
6.	進口商/出口商須要爲某些指定的高風險或容易被誤用的醫療儀器領取進口 / 出口許可證。 Importers/exporters of medical devices are required to obtain import /export licences for specified medical devices that are of high risk or may be subject to misuse.	□	□	□

7. 其他意見:
Other comments:

完

END

個人資料(私隱)條例
用途聲明

1. 收集資料的目的

你與衞生署溝通互動時所提供的個人資料，會用於衞生署作爲行政及/或立法規管醫療儀器的用途。

2. 資料轉介人的類別

你所提供的個人資料，衞生署主要作內部用途，但也可能於有所需要時因以上第 1 段所列目的或有關事項向其他政策局/部門，或有關方面披露。此外，該等資料只可於你同意作出該種披露或作出該種披露是《個人資料(私隱)條例》所允許的情況下，才向其他方披露。

3. 查閱個人資料

根據《個人資料（私隱）條例》第 18 條及 22 條以及附表 1 第 6 原則所述，你有權查閱及修正個人資料，包括有權取得你於以上第 1 段所述的情況下所提供的個人資料。因應查閱資料要求而提供資料時，衞生署可能要徵收費用。

4. 查詢

就已提供的個人資料的查詢，包括索閱或更改資料，可向 衞生署醫療儀器管制辦公室(香港灣仔皇后大道東 183 號合和中心 31 樓 3101 室，傳真號碼：3157 1286，電話號碼：3107 8484) 提出。

Personal Data (Privacy) Ordinance

Statement of Purposes

1. Purpose of Collection

The personal data that are provided by you with whom the Department of Health (DH) interacts will be used by the DH for the purposes of administrative and/or statutory control of medical devices.

2. Classes of Transferees

The personal data that you provide are mainly for use within the DH but it may also be disclosed to other Government bureaux/departments or relevant parties for the purposes mentioned in para. 1 above, and related matters if required. Apart from this, the data may only be disclosed to parties where you have given consent to such disclosure or where it is allowed under the Personal Data (Privacy) Ordinance.

3. Access to Personal Data

You have a right of access and correction with respect to personal data as provided for in sections 18 and 22 and Principle 6 of Schedule 1 of the Personal Data (Privacy) Ordinance. Your right of access includes the right to obtain a copy of your personal data. A fee may be imposed for complying with a data access request.

4. Enquiries

Enquiries concerning the personal data provided, including the making of access and corrections, should be addressed to the Medical Device Control Office, Department of Health (31/F., Hopewell Centre, 183 Queen's Road East, Wanchai, Hong Kong; fascimile number: 3157 1286; telephone number: 3107 8484).