

# LANGUAGE REQUIREMENTS FOR MEDICAL DEVICES: ASIA

| Country     | Language Labeling Requirement  | Competent Authority   | US Commerical Service Device Specialist  |
|-------------|--|---|--|
| China       | Chinese & English<br><i>(both required)</i>  | <b>State Food and Drug Administration</b><br>Phone: +86-10-6831-3344<br>Fax: +86-10-6831-0909<br>Web: <a href="http://www.sfda.gov.cn/eng">www.sfda.gov.cn/eng</a><br><br>Address: A38, Beilishi<br>Beijing 100810<br>P.R. China  | <b>US Commercial Service – Beijing</b><br>Contact: Shuyu Sun<br>Phone: +86-10-8529-6655 ext 852<br>Fax: +86-10-8529-6558<br>Email: <a href="mailto:Shuyu.Sun@mail.doc.gov">Shuyu.Sun@mail.doc.gov</a><br><br>Address: US Commercial Service<br>31st Floor, North Tower<br>Beijing Kerry Center,<br>Beijing, China 100020   |
| Cambodia    | Khmer  | <b>No Competent Authority as of January 2005</b>  |  |
| Hong Kong   | Chinese & English<br><i>(Both languages are preferred, but the labeling shall be in at least one of these languages)</i> | <b>Department of Health of Hong Kong</b><br>Phone: +852-2961-8894<br>Web: <a href="http://www.info.gov.hk/dh">www.info.gov.hk/dh</a><br><br>Address: 32nd Floor, Wu Chung House<br>213 Queen's Road East<br>Wan Chai<br>Hong Kong   | <b>US Commercial Service – Hong Kong</b><br>Contact: Ms. Rose Pak<br>Phone: +852-2521-1467<br>Fax: +852-2845-9800<br>Email: <a href="mailto:Rose.Pak@mail.doc.gov">Rose.Pak@mail.doc.gov</a><br><br>Address: American Consulate General<br>26 Garden Road<br>Central, Hong Kong (SAR)  |
| India       | English  | <b>Ministry of Health and Family Welfare</b><br>Department of Health<br>Phone: +91-11-301-0661 (General)<br>Phone: +91-11-301-3800 (Office, Drugs Controller)<br>Web: <a href="http://www.mohfw.nic.in/depth.htm">www.mohfw.nic.in/depth.htm</a><br><br>Address: A-Wing, Nirman Bhavan<br>New Delhi 110001, India   | <b>US Commercial Service – New Delhi</b><br>Contact: Srimoti Mukherji<br>Phone: +91-11-2331-6841 ext 2226<br>Fax: +91-11-2331 5172<br>Email: <a href="mailto:Srimoti.Mukherji@mail.doc.gov">Srimoti.Mukherji@mail.doc.gov</a><br><br>Address: The American Center<br>24 Kasturba Gandhi Marg<br>New Delhi 110 001  |
| Indonesia   | English & Indonesian   | <b>Ministry of Health of the Republic of Indonesia</b><br>Directorate General of Pharmacy and Medical Devices Services<br>Phone: +62-21-520-1590 ext 7201<br>Fax: +62-21-922-7224<br>Web: <a href="http://www.depkes.go.id">www.depkes.go.id</a> (Indonesian Only)<br><br>Address: Jalan H.R. Rasuna Said Blok X-5<br>Kav. No. 4-9, Lantai 7/720<br>Jakarta 12950, Indonesia                            | <b>US Commercial Service – Jakarta</b><br>Contact: Sharon Chandra<br>Phone: +62-21 526 2850 ext 3007<br>Fax: +62-21 526 2855<br>Email: <a href="mailto:Sharon.Chandra@mail.doc.gov">Sharon.Chandra@mail.doc.gov</a><br>Email: <a href="mailto:Jakarta.Office.Box@mail.doc.gov">Jakarta.Office.Box@mail.doc.gov</a><br><br>Address: American Embassy<br>US Commercial Service<br>Wisma Metropolitan II, 3rd Floor<br>Jl. Jendral Sudirman Kav. 29-31<br>Jakarta 12920 |
| Japan       | Japanese   | <b>Pharmaceuticals and Medical Devices Agency</b><br>Phone: +81-3-3506-9541<br>Fax: +81-3-3506-9417<br>Web: <a href="http://www.pmda.go.jp">www.pmda.go.jp</a><br><br>Address: Shin-Kasumigaseki Building<br>3-3-2 Kasumigaseki, Chiyoda-ku,<br>Tokyo 100-0013, Japan   | <b>US Commercial Service – Tokyo</b><br>Contact: Hiroyuki Hanawa<br>Phone: +81-3-3224-5060<br>Fax: +81-3-3589-4235<br><br>Address: American Embassy<br>1-10-5 Akasaka, Minato-ku,<br>Tokyo 107-8420, Japan   |
| South Korea | Korean   | <b>Korea Food &amp; Drug Administration</b><br>Medical Devices & Radiation Health Department<br>Medical Device Standards Division<br>Phone: +82-2-380-1754<br>Fax: +82-2-351-3726<br>Medical Devices Division<br>Phone: +82-2-380-1519<br>Fax: +82-2-388-6394<br>Web: <a href="http://www.kfda.go.kr">www.kfda.go.kr</a><br><br>Address: 5 Nokbun-dong, Eunpyung-ku<br>122-704 Seoul, Republic of Korea | <b>US Commercial Service – Seoul</b><br>Contact: Yoon Shil Chay<br>Phone: +82-2-397-4439<br>Fax: +82-2-737-5357<br>Email: <a href="mailto:Yoon.Shil.Chay@mail.doc.gov">Yoon.Shil.Chay@mail.doc.gov</a><br><br>Address: American Embassy<br>US Commercial Service<br>32, Sejong-ro, Chongro-ku<br>Seoul 110-710   |
| Malaysia    | Malaysian  | <b>Ministry of Health, Malaysia</b><br>Engineering Services Division<br>Phone: +60-3-2694-9304<br>Fax: +60-3-2694-9317<br>Web: <a href="http://www.moh.gov.my">www.moh.gov.my</a> (Malaysian Only)<br><br>Address: 4th & 6th Floor, Wisma Sime Darby<br>Jalan Raja Laut, Malaysia   | <b>US Commercial Service – Kuala Lumpur</b><br>Contact: Natila Ahmad<br>Phone: +60-3-2168-5101<br>Fax: +60-3-2142-1866<br>Email: <a href="mailto:Natila.Ahmad@mail.doc.gov">Natila.Ahmad@mail.doc.gov</a><br><br>Address: American Embassy<br>US Commercial Service<br>376 Jalan Tun Razak 50400<br>Kuala Lumpur   |

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|-------------|---|---|---|
| Philippines | English<br>Or<br>Equivalent Filipino              | <b>Department of Health, Republic of the Philippines</b><br>Bureau of Health Devices and Technology<br>Phone: +63-2-743-8301<br>Web: <a href="http://www.doh.gov.ph/bhdt">www.doh.gov.ph/bhdt</a><br><br>Address: Bldg. 24 San Lazaro Cpd.<br>Rizal Avenue, Sta. Cruz<br>Manila 1003<br>Philippines   | <b>US Commercial Service - Manila</b><br>Contact: Dey Robles<br>Phone: +63-2-888-4088 ext 5828<br>Fax: +63-2-888-6606<br>Email: <a href="mailto:Dey.Robles@mail.doc.gov">Dey.Robles@mail.doc.gov</a><br><br>Address: American Embassy<br>25/F Ayala Life-FGU Center<br>6811 Ayala Avenue<br>Makati City 1226<br>Philippines                                     |
| Singapore   | English<br><i>(Submission Documents)</i>          | <b>Health Sciences Authority (HSA)</b><br>Centre of Medical Device Regulation (CMDR)<br>Phone: +65-6866-3560 (medical devices)<br>Fax: +65-6478-9028<br>Website: <a href="http://www.hsa.gov.sg">www.hsa.gov.sg</a><br><br>Address: 11 Biopolis Way<br>#11-03 Helios<br>Singapore 138667  | <b>US Commercial Service – Singapore</b><br>Contact: Luanne Theseira<br>Phone: +65-6476-9416<br>Fax: +65-6476-9080<br>Email: <a href="mailto:Luanne.Theseira@mail.doc.gov">Luanne.Theseira@mail.doc.gov</a><br><br>Address: American Embassy<br>US Commercial Service<br>27 Napier Road<br>Singapore 258508   |
| Taiwan      | Chinese   | <b>Department of Health</b><br>Bureau of Pharmaceutical Affairs 2nd Division<br>Phone: +886-2-2321-0151<br>Fax: +886-2-2397-1548<br>Web: <a href="http://www.doh.gov.tw">www.doh.gov.tw</a><br><br>Address: No. 100, Aikuo E. Road<br>Taipei, Taiwan  | <b>US Commercial Service – Taipei</b><br>Contact: Angeli Chou<br>Phone: +886-2-2720-1550 ext 310<br>Fax: +886-2-2757-7162<br>Email: <a href="mailto:Angeli.Chou@mail.doc.gov">Angeli.Chou@mail.doc.gov</a><br><br>Address: American Institute in Taiwan<br>Suite 3207<br>333 Keelung Road Section 1<br>Taipei, Taiwan   |
| Thailand    | Thai  | <b>Ministry of Public Health</b><br>Food and Drug Administration<br>Medical Device Control Division<br>Phone: +662-590-7245<br>Fax: +662-591-8480<br>Web: <a href="http://eng.moph.go.th">http://eng.moph.go.th</a><br><br>The Medical Device Act can be viewed at:<br><a href="http://www.fda.moph.go.th/eng/index.stm">www.fda.moph.go.th/eng/index.stm</a><br><br>Address: Tivanont Road<br>Muang, Nonthaburi 1100<br>Thailand | <b>US Commercial Service – Bangkok</b><br>Contact: Nalin Phupoksakul<br>Phone: +662-205-5275<br>Fax: +662-255-2915<br>Email: <a href="mailto:Nalin.Phupoksakul@mail.doc.gov">Nalin.Phupoksakul@mail.doc.gov</a><br><br>Address: American Embassy<br>US Commercial Service<br>Diethelm Tower A, Suite 301-302<br>93/1 Wireless Road,<br>Pathumwan, Bangkok 10330 |
| Vietnam     | English & Vietnamese<br>Or<br>French & Vietnamese | <b>Ministry of Health of Vietnam</b><br>Phone: +84-4-846-4416<br>Fax: +84-4-846-4051<br>Web: <a href="http://www.moh.gov.vn/English">www.moh.gov.vn/English</a><br><br>Address: 138 Giang Vo,<br>Ba Dinh, Ha Noi<br>Vietnam   | <b>US Commercial Service – Saigon</b><br>Contact: Le Anh<br>Phone: +84-8-825-0490<br>Fax: +84-8-825-0491<br>Email: <a href="mailto:Le.Anh@mail.doc.gov">Le.Anh@mail.doc.gov</a><br><br>Address: American Consulate General<br>US Commercial Service<br>Saigon Center 9F<br>65 Le Loi Boulevard, District 1<br>Ho Chi Minh City<br>Vietnam                       |

Labeling Requirements & All Contact Information current as of 1/1/2005

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1.877.824.8800 (San Francisco)