



Medical Device Regulatory Requirements for India

Updated: 10/13/00.

Disclaimer: The information contained on this website is derived from public sources and is current to the best of our knowledge. For detailed and definitive information about a country's laws and policies, the government of the country concerned should be consulted.

Currently, India does not regulate the sale of medical devices. India accepts non-U.S. Food & Drug Administration-approved as well as non-CE-marked medical devices (however, in accordance with U.S. FDA requirements, U.S. manufacturers may only export to India and to other countries medical devices that have been approved either by the USFDA or another FDA- designated "Tier-1" country, i.e., Australia, Canada, Israel, Japan, New Zealand, Switzerland, South Africa, or any member nation in the European Union or the European Economic Area).

Under India's Ministry of Health and Family Welfare, the Department of Health has nominal jurisdiction over medical device regulation, and reportedly is considering the introduction of a separate regime of regulations for medical devices (currently, the Ministry regulates pharmaceuticals under authority of India's Drug and Cosmetics Act, and pharmaceuticals must be specifically registered in order to be sold in India). We will seek to update this page as any further new information warrants.

Indian tariffs for medical devices remain relatively high. While devices designated as "life-saving equipment" are eligible for duty-free treatment, and some other devices not manufactured in India are eligible for 10 percent tariffs. However, many devices can face tariffs ranging from 20 to as high as 40 percent.

Contacts:

Ministry of Health and Family Welfare
Department of Health
A-Wing, Nirman Bhavan
New Delhi 110001, India
Tel: 91-11-301-0661 (General)
Tel: 91-11-301-3800 (Office of the Drugs Controller)

Appendix 1: For additional information, read the 2005 Commercial Service Reports.

[India Cancer Diagnostic Equipment](#)

[India Health Care Indicators](#)

[India Diagnostic Laboratory Market](#)

India Medical Equipment and Diagnostics: Registration and Documentation Required for Import

Last updated on 12-20-05 by JF

[Contact Us](#) [Privacy Statement](#) [Endorsement Policy](#)

[U.S. Department of Commerce](#) [International Trade Administration](#) [Manufacturing and Services](#)