

**[ DOH ADMINISTRATIVE ORDER NO. 2007-0003,  
January 08, 2007 ]**

**POLICIES AND GUIDELINES GOVERNING THE REGISTRATION  
AND LICENSING OF ESTABLISHMENTS DEALING WITH MEDICAL  
DEVICES**

**I. RATIONALE**

The State is mandated (a) to adopt an integrated and comprehensive approach to health development which shall endeavor to make essential goods, health and, other social services available to all the people at affordable cost (Section 11, Article II, 1987

Constitution); (b) to establish and maintain an effective food and drug regulatory system; (c) to undertake appropriate health manpower development and research responsive to the country's health needs and problems (Section 12, Article XIII, 1987 Constitution).

In view thereof, Republic Act No. 3720, as amended by Executive Order No. 175, otherwise known as the "Food, Drugs and Devices and Cosmetic Act" was enacted to establish an effective system in the registration, monitoring, and regulation of food, cosmetics, drugs, devices, and household hazardous substances.

On May 24, 1999, then President Joseph Ejercito Estrada issued Executive Order No. 102, series of 1999 purposely to redirect the functions and operations of the Department of Health, as a result of which the Bureau of Health Devices and Technology (BHDT) was created with regulation of medical and health-related devices as one of its major functions.

Thus, issues concerning the registration of medical devices and licensing of medical device establishments have been raised that have effectively impeded the achievement of the abovementioned constitutional mandate and objectives. It is further realized that there is a necessity to give particular attention to medical devices in the Philippines not only in consonance with the ongoing regional and global harmonization efforts but in relation to the enhancements made by science in medical technology and in line with the efforts being made to rationalize and streamline the operations and capacities of the Department of Health, in general, and the Bureau of Food and Drugs (BFAD) and the BHDT, in particular, which should result in better health outcomes for Filipinos. In view of the above premises, this order is hereby issued.

**II. PURPOSE AND OBJECTIVE**

The purpose of this Order is to harmonize the provisions of R.A. No. 3720, as amended, and E.O. No. 102, s. 1999 by establishing policies and guidelines