

**[ DOH ADMINISTRATIVE ORDER NO. 2005-003,  
January 11, 2005 ]**

**GUIDELINES ON THE ISSUANCE OF CERTIFICATE OF PRODUCT  
REGISTRATION FOR WATER PURIFICATION EQUIPMENT AND  
DEVICE**

**I  
RATIONALE**

Pursuant to the provisions of the Revised Implementing Rules and Regulations of Chapter II - "Water Supply" of the Sanitation Code of the Philippines (P.D. 856), the Department of Health through the Bureau of Health Devices and Technology is hereby mandated to implement these guidelines on the issuance of Certificate of Product Registration for water purification equipment, and devices including household water filters and water purifiers.

**II  
SCOPE/COVERAGE**

These guidelines shall apply to local manufacturers, importers and distributors, including establishments that repackage and re-label water purification equipment, and devices including household water filters and water purifiers for the purpose of selling or commercial distribution in the local market.

**III  
DEFINITION OF TERMS**

As used in this set of guidelines, the terms below shall be defined as follows:

**APPLICANT** - refers to a local or foreign establishment that seeks to include its health related device in the BHDT list of registered water purification devices.

**BHDT** - refers to the Bureau of Health Devices and Technology (BHDT) of the Department of Health.

**CERTIFICATE OF PRODUCT REGISTRATION** - a certification issued by the Secretary of Health or his duly authorized representative, the Director of BHDT, attesting the claims of the manufacturer, importer or distributor on the product. Claims can be found in the label and the manual of the product.

**DISTRIBUTOR** - refers to any person or establishment to whom or where a water purification device product is delivered or sold for purposes of distribution in commerce, except that such term does not include a manufacturer or retailer of such product.

**HRDRD** - refers to the Health Related Device Regulation Division of the Bureau of Health Devices and Technology of the Department of Health.

**IMPORTER** - refers to any person or business establishment that receives water purification devices from foreign manufacturers for the purpose of offering them for sale and/or distribution in the Philippines.

**LABELING** - display of written, printed or graphic matter, printed or graphic matter on any water purification device product, its immediate container, tag, literature or other suitable material affixed thereto for the purpose of giving information as to the identity, components, attributes, directions for use, specification and such other information as may be required by law or regulations.

**MANUFACTURER** - refers to any person who manufactures, assembles or processes water purification devices, except that if such products are manufactured, assembled or processed for another person who attaches his own brand name to the product, the latter shall be deemed the manufacturer. In case of imported products, the manufacturer's representative or, in his absence, the importer shall be deemed the manufacturer.

**WATER SYSTEM COMPONENTS** - materials or products that come in contact with drinking water, drinking water treatment chemicals, or both which include, but are not limited to, process media (carbon, sand etc.), protective materials (coatings, linings, liners, etc), joining and sealing materials (solvent cement, welding materials, gaskets, etc), devices used in storing and dispensing water (tanks, water dispenser, etc) and devices used in treatment/transmission/distribution systems (fittings, valves, chlorinators, separation members, etc.)

**WATER PURIFICATION DEVICES** - equipment, apparatus, device or gadget whose purpose is to purify or treat water, either for household, commercial or other uses.

**WATER PURIFICATION SYSTEM** - combination of water purification devices and water system components intended to purify or treat water for drinking purposes.

#### **IV GENERAL REQUIREMENTS**

**A. All local manufacturers, importers and distributors, including establishments that repackage and re-label water purification equipment, and devices including household water filters and water purifiers shall apply for Certificate of Product Registration to the Department of Health through the Bureau of Health Devices and Technology that fall under any of the following conditions:**

1. Water purification devices and water purification system that are already in the market prior to the publication of this guideline.
2. When introducing a device or a system into commercial distribution for the first time.
3. When proposing an additional use for the device that is already in the market. Additional use is indicated in the new label/labeling of the device.
4. When there is a change or modification of a device or a system the manufacturer already markets, if that change could significantly affect its safety or effectiveness