



Charlie Crist
Governor

Ana M. Viamonte Ros, M.D., M.P.H.
State Surgeon General

IMPORTANT NOTICE!

TO: All Device Manufacturer Permit (license) Holders
FROM: Rebecca Poston, Executive Director - Drugs, Devices, and Cosmetic Program
DATE: June 23, 2010
RE: Law Change Creating Permit Exemptions

Effective July 1, 2010, a Device Manufacturer permit is no longer required if your medical device manufacturing establishment meets certain conditions.

On May 28, 2010, Governor Crist signed House Bill 5311 into law. This bill amended Section 499.01(2)(q), Florida Statutes (F.S.) exempting device manufacturers from a permit if they meet the following conditions outlined in the underlined text of the new law below.

A Device Manufacturer permit is not required if:

- a. The person is engaged only in manufacturing, repackaging, or assembling a medical device pursuant to a practitioner's order for a specific patient; or
- b. The person does not manufacture, repackage, or assemble any medical devices or components for such devices, except those devices or components which are exempt from registration pursuant to s. 499.015(8), F.S.

For your reference, section 499.015(8) reads as follows:

- (8) Notwithstanding any requirements set forth in this part, a manufacturer of medical devices that is registered with the federal Food and Drug Administration is exempt from this section and s. 499.041(6) if:
 - (a) The manufacturer's medical devices are approved for marketing by, or listed with the federal Food and Drug Administration in accordance with federal law for commercial distribution; or
 - (b) The manufacturer subcontracts with a manufacturer of medical devices to manufacture components of such devices.

A permit is not required if your establishment is registered with the federal Food and Drug Administration (FDA) and only manufactures, repackages, or assembles any medical device or component thereof that is approved for marketing or listed with the FDA in accordance with federal law for commercial distribution.

If you meet the above criteria for exemption and receive a renewal notice for your Device Manufacturer permit, you are not required to renew your permit. No further action is required. Your permit will automatically expire and become null and void.

If you need to communicate with staff, you are encouraged to email mqa_ddc@doh.state.fl.us or you may call us at 850-245-4292.