**Section 211.3705 Medical Device**

"Medical Device" means, for purposes of 35 Ill. Adm. Code 218.187 and 219.187, an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent or other similar article, including any component or accessory, that meets one or more of the following conditions:

a) it is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease;

b) it is intended to affect the structure or any function of the body; or

c) it is defined in the National Formulary or the United States Pharmacopeia, or any supplement to them.

(Source: Added at 34 Ill. Reg. 9069, effective June 25, 2010)