Regulations] [Title 21, Volume 8] [Revised as of April 1, 2003] From the U.S. Government Printing Office via GPO Access [CITE: 21CFR880.2800]

TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

PART 880--GENERAL HOSPITAL AND PERSONAL USE DEVICES

Subpart C--General Hospital and Personal Use Monitoring Devices

Sec. 880.2800 Sterilization process indicator.

(a) Biological sterilization process indicator--(1) Identification.
A biological sterilization process indicator is a device intended for use by a health care provider to accompany products being sterilized through a sterilization procedure and to monitor adequacy of sterilization. The device consists of a known number of microorganisms, of known resistance to the mode of sterilization, in or on a carrier and enclosed in a protective package. Subsequent growth or failure of the microorganisms to grow under suitable conditions indicates the adequacy of sterilization.

(2) Classification. Class II (performance standards).

(b) Physical/chemical sterilization process indicator--(1) Identification.
A physical/chemical sterilization process indicator is a device intended for use by a health care provider to accompany products being sterilized through a sterilization procedure and to monitor one or more parameters of the sterilization process. The adequacy of the sterilization conditions as measured by these parameters is indicated by a visible change in the device.

(2) Classification. Class II (performance standards).