

February 8, 2021

To Whom It May Concern,

According to the European Directive 93/42/EEC, indicators are not considered medical devices. Article 1 of the Directive defines medical devices as being:

“any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation or compensation for an injury or handicap,
- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception, and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means”

Article 1 also defines an accessory as “an article which, whilst not being a medical device, is intended specifically by its manufacturer to be used together with a device to enable that device to be used in accordance with its intended use.”

As such, all current member states of the European community share the opinion that a chemical and biological indicator are not medical devices or accessories.

Kind Regards,

Jon Rutigliano

Electronically signed by: Jon Rutigliano
Reason: I created this document.
Date: Feb 8, 2021 09:37 MST

Jon Rutigliano
Director, Quality Assurance
SteriTec Products Manufacturing CO Inc.
74 Inverness Dr East
Englewood, CO 80112