

**MANUAL ON BORDERLINE AND CLASSIFICATION IN THE COMMUNITY
REGULATORY FRAMEWORK FOR MEDICAL DEVICES
Version 1.16 (07-2014)**

7.4. Sterilization indicators

- Background

The sterilization procedure is monitored routinely by using chemical and biological indicators to evaluate the sterilizing conditions and indirectly the microbiologic status of the processed items.

- Outcome

Sterilization indicators monitor the performance of the sterilizer. They do not affect the sterilization procedure and only provide additional information to the user.

Sterilization indicators do not fulfil either the definition of a medical device laid down in Article 1(2)a of Directive 93/42/EEC or the definition of an accessory laid down in Article 1(2)b of Directive 93/42/EEC as they are not intended specifically to be used together with a device to enable it to be used in accordance with its stated use.