METHOD FOR MANUFACTURING A STERILIZED AND CALIBRATED BIOSENSOR-BASED MEDICAL DEVICE

ABSTRACT OF THE DISCLOSURE

A method for manufacturing a sterilized and calibrated biosensor-based medical device (e.g., an integrated biosensor and lancet medical device) includes sterilizing a biosensor-based medical device that contains a biosensor reagent composition (e.g., an analyte specific enzyme and mediator biosensor reagent composition). The sterilizing can be accomplished using, for example, a gamma radiation based technique. Thereafter, the biosensor reagent composition of the sterilized biosensor-based medical device is calibrated. Another method for manufacturing a sterilized and calibrated biosensor-based medical device includes first assembling and packaging a plurality of biosensor-based medical devices that include a biosensor reagent composition. The packaged biosensor-based medical devices are then sterilized using a radiation-based sterilization technique, to create a plurality of sterilized, packaged biosensor-based medical devices. Thereafter, the sterilized and packaged biosensor-based medical devices are calibrated. The calibration can be accomplished, for example, using a statistical sample of the plurality of sterilized, packaged biosensor-based medical devices.

Figure 3