Gmail BGHMC BAC III <bghmcbac3@gmail.com>

Medical Device Verification

Roda Santos Pascua <rspascua@fda.gov.ph> 29 June 2022 at 11:32
To: BGHMC BAC III <bghmcbac3@gmail.com>
Cc: Center for Device Regulation Radiation and Health Research <cdrrhr@fda.gov.ph>, "Ma. Cecilia Matienzo C." <mccmatienzo@fda.gov.ph>

Dear Sir/Ma'am:

All reusable surgical instruments which are not connected to any active medical device are classified as **Class A Medical Devices**. Reusable Surgical Instrument is defined in the ASEAN Medical Device Directive as:

REUSABLE SURGICAL INSTRUMENT : Instrument intended for surgical use by cutting, drilling, sawing, scratching, scraping, clamping, retracting, clipping or other surgical procedures,
without connection to any active medical device and which are intended by the product owner to be reused after appropriate procedures for cleaning and/or sterilisation have been carried out.

For those containers that are being used to collect body wastes and these body wastes are not intended for laboratory tests, are not considered as medical devices. Example: Emesis Kidney Basin. This is not a medical device because its intended use is to collect the runoff from medical procedures involving the application of liquid to the body.

Thank you.

Roda S. Pascua
Engineer III
Licensing and Registration Division
Center for Device Regulation Radiation Health and Research
Food and Drug Administration

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You may also access the form using this link FDA Customer Satisfaction Survey.