

INDUSTRY

Medical Devices

Bioburden, particle and residue control in medical device manufacturing and assembly.



DATASHEET PER PART NUMBER



STANDARDS REFERENCED



RECURRING CONSUMPTION

A medical device is manufactured twice: the product, and the record showing how it was made. Environmental cleanliness is part of both, because the microbial load the product carries into sterilisation determines whether the chosen sterilisation cycle is enough.

PRODUCTS FOR THIS INDUSTRY



VANTERIS 3-Ply Pleated Face Mask, Blue

VNT-73P-BL-50
17.5 × 9.5 cm



VANTERIS Polyester Wipe 9 × 9 in
VTN-WP-PES-LS-99

9 × 9 in (228.6 × 228.6 mm)



VANTERIS Sticky Mat 24 × 36 in, Blue
VTN-MAT-PE-STK-2436-BLU

24 × 36 in



VANTERIS Beard Cover 18 in, White
VTN-AP-PP-BRD-UNI-WHT

18 in

TYPICAL CHALLENGES

- Bioburden before sterilisation
- Adhered particles on implantable product
- Extractables and biocompatibility
- Consumable traceability and change control

REFERENCE STANDARDS

ISO 13485	Quality management system for medical devices.
ISO 11737-1	Determination of the population of microorganisms on product.
ISO 10993	Biological evaluation of medical devices.
IENT-RP-CC003	Garment systems for cleanrooms and controlled environments.

VANTERIS

ventas@vanteris.mx

Francisco Márquez 16138, int. BA13, Valle Vista 1ra Secc.
22456 Tijuana, B.C., México

Monday to Friday, 08:00 – 17:00

Technical article and catalog

