

USP 797 & 800 Compliance Specialists

Everything you need to achieve and maintain a compliant cleanroom environment

Sterile Pouch Style Facemask

with Headloop, Gamma Irradited

DB™ Sterile Pouch-style Facemask BDBS

About

Constructed with a patented spacer to maintain clear breathing space, the BioClean DB™ Sterile Pouch-style Facemask ensures exceptional breathability, comfort, and protection for the wearer.

Materials

INNER FACING LAYER:

Non-woven spunbonded polyester (hygroscopic)

FILTER LAYER:

Meltblown polyester

OUTER FACING LAYER:

Non-woven spunbonded polyester (hydrophobic)

FASTENINGS:

Tubular knitted polyurethane Spandex yarn headloops

NOSE-BAND:

Plastic coated steel

Features

- Latex-free
- Patented spacer maintains clear breathing space
- Ultrasonically sealed edges
- Low-linting
- Fully enclosed malleable nose band
- ISO Class 4 & EU GMP Grade A compatible







Carter-Health Disposables, LLC Phone: (407) 296.6689 Web: www.Carter-Health.com

Quality Standards

- Manufactured in a facility holding ISO 9001:2008
- Processed in an NEBB certified ISO Class 4 cleanroom environment
- Sampling and inspection in accordance with ISO 2859-3:1991

Sterilization

Method: Gamma irradiation Minimum Dose: 25kGy

Sterility Assurance Level: 10⁻⁶

Shelf Life & Storage

Five (5) years from date of manufacture. Store in a dry, cool place (<40°C) away from direct sunlight and fluorescent light.

Physical Properties

COLOUR	White
STYLE	Headloops
LENGTH (± 5mm)	301mm
WIDTH (± 5mm)	100mm

Performance Information

COMPATIBILITY	ISO Class 4 & EU GMP Grade A
PARTICLE FILTRATION EFFICIENCY (PFE)@ 0.3 MICRON	98.2%
BACTERIAL FILTRATION EFFICIENCY (BFE) @ 3.0 MICRON	97.9%
VIRAL FILTRATION EFFICIENCY (VFE)	98.5%
DIFFERENTIAL PRESSURE (△P), mm H₂0/cm²	3.57



