

cGMP Documentation



Materials verification package (HEPA filter, motor blower, powder coating, SS lot, calibration of the pressure gauge)

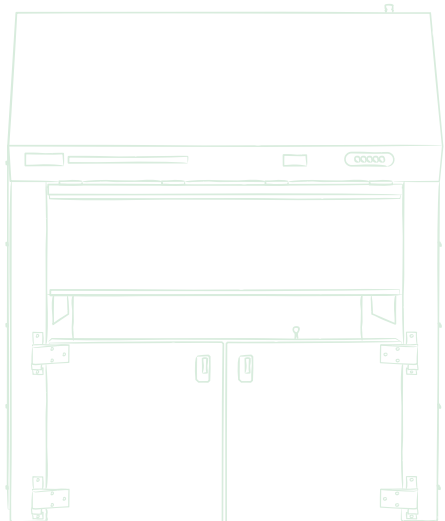


IQ/OQ documents (Protocol Only or Protocol, Execution & Report)

Need an ISO Class 5 / Grade A Aseptic Processing Environment?

Talk to Baker Today!

Contact information/notes:



~ BioPROTECT e3 - Larger scale enclosure available for GMP instrumentation



Check Baker's BSC MythBusters:
Common Disinfectant Chemical
Compatibility with Stainless Steel



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Best available technology... demonstrated!

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For Aseptic Biopharmaceutical Processing



Ideal for cell and gene therapy and personalized medicine.

SterilGARD® e3
BioPharma Package

SterilGARD® e3

Class II Type A2 Biosafety Cabinets

Providing cGMP / cGLP engineering solutions with the SterilGARD® e3 by selecting standard and optional features.

Standard Features

- (-)Pressure double wall plenum
- Internal GFCI duplex outlet
- Audible and visual alarms
- Momentum air curtain
- High-velocity return air slots
- Removable work surface
- ReadySafe™ low-flow operating mode
- StediFlow™ - VFD motor controller
- UniPressure™ - preflow plenum
- SS air bypass

cGMP Optional Features

- All stainless steel (SS) construction 304 or 316, interior or exterior
- SS cable port(s) & sleeves
- Isokinetic sampling probe / shelf for counter is possible under drain pan
- Microbial sampling of viable particles
- Cabinet set point monitor with BAS / BMS connectivity
- SS channel stand
- Minimal penetrations in work area
- Green status light - visual indicator for operator of fully operational mode
- Patch Free HEPA filters
- SS Casters
- SS Needle Valve and Piping
- H202 Decon Injection Ports

Complies with NSF International Standard 49.

Baker is a component provider and is not responsible for cGMP compliance.

Create an ISO Class 5 / Grade A Aseptic Processing Environment*

CABINET SET POINT MONITOR

Digital Pressure Gauge option upgrade with output signal for BAS / BMS connectivity

MINIMAL PENETRATIONS IN WORK AREA

Reducing the amount of penetrations or punctures through the steel to give multiple options for optimal cleanability

STAINLESS STEEL OUTLET COVER

STAINLESS STEEL CHANNEL STAND

Increased chemical resistance & cleanability

STAINLESS STEEL AIR BYPASS

Sight-tight air bypass for closed sash operation

BMS CABLE INTERFACE ASSEMBLY

Cable Package providing dry contacts to send signal to turn on exhaust blower on roof, alert a power failure, alert blower is operational or signify cabinet is in Ready Safe Mode

ALL STAINLESS STEEL CONSTRUCTION

Increased cleanability and resistance to corrosion

ISOKINETIC SAMPLING PROBE

Provides continuous non-viable particle counting mandated for aseptic manufacturing

STAINLESS STEEL CABLE PORT(S) & SLEEVES

To facilitate tubing and cabling needs under negative pressure

Talk to us about the features presented and how they can help you work towards cGMP / cGLP

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*per ISO 14644