

# Certificate of Conformance

**For Pharmaceutical Grade TETPOR AIR DEMI Filters**

**Rated to 0,2 Micron(s)**

*This certifies that the **domnick hunter** filter ZCMTA-020Z-A  
35 pieces*

Your order nr.: 237/1379711/ our accept. AB97679

Has been manufactured in a purpose-built facility within a controlled environment and subjected to a purified water flush.

## Materials of Construction

All components of this cartridge are manufactured from materials suitable for contact with food and conform to the biological safety requirements laid down in the current USP Class VI – 121°C Plastics. They also conform with the requirements for non fibre releasing filters as laid down in the United States FDA Title 21 CFR 211.72 and 210.3(b), (6).

The filters also meet the domnick hunter quality control and assurance standards:

## Product Integrity

This product has successfully passed a non-destructive integrity test, which for sterilising grade cartridges is Correlated to a bacterial challenge which gave a sterile effluent when challenged with a minimum of  $10^7$  organisms per sq cm.

The maximum diffusional flow value for this product is 6 mL/min at the test pressure of 800 mbar

During validation, filter samples underwent the following tests and satisfactorily met the respective criteria specified : -

### Effluent Quality

#### TOC

Met the requirements of USP Total Organic Carbon <643>

### Bacterial Endotoxins

Cartridge aqueous extraction contains less than 0,125 EU/ml as determined using the Limulus Amebocyte Lysate (LAL) test, which meets the requirements of USP Water for Injection.

### Water Conductivity

Met the requirements of USP Water Conductivity <645>

### Particle Release

Met the requirements of USP Particulate Matter in Injections <788>

### Thermal Stability

Integrity was maintained after 120 steam cycles of 30minutes at 142°C

This Product is registered with the Food & Drug Administration Drug Master File 7564



Signature .....

-Product Manager-

Date March 2009

For and on behalf of:

**domnick hunter ltd.**

PROCESS DIVISION

Durham Road, Birtley; Co. Durham, England DH3 2SH

Telephone: +44 (0) 191-410 5121 ; Telefax: +44 (0) 191-4105312