

January 2014

To whom it may concern:

The complete range of Intersurgical breathing filters has been validated against the passage of a variety of bacterial and viral species of varying particle sizes.

The Clear-Therm 3 HMEF device (code 1541000 ) has been independently validated against the passage of Bacillus subtilis (1.0μm x 0.7μm) and φ174 bacteriophage (0.027µm) to represent the bacterial and viral challenge it may face in the clinical environment. These tests show the filter to be >99.99% efficient against these challenge organisms.

The challenge presented in the viral test protocol (φ174 bacteriophage, 0.027 μm) will be at least as severe as that posed by the Hepatitis C virus (0.030 -0.080μm) or by Mycobacterium tuberculosis (0.2- 2μm) because it is a smaller particle.

As such, it can be concluded that the 1541 range of products will provide at least the same level of quoted efficiency (>99.99%) as reported in the independent microbiology tests when challenged with Hepatitis C and M. tuberculosis. Copies of these test protocols are available upon request.

Should you require further information or clarification please do not hesitate to contact me. Thank you.

Yours sincerely

Sean Duggan

Filter Product Manager

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Intersurgical



