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To whom it may concern

Sterility of Ecobag® IV

Dear Sir or Madam,

Thank you very much for your request concerning the sterility of Ecobag® IV.

Ecobag® IV is sterilized within its overwrap with moist heat in overkill conditions ($F_{0\geq 15}$ minutes).

Internal microbiological studies evaluated the microbial reduction in the space between the primary bag and the overwrap. As recommended by ISO 11138-3:2007, *Geobacillus stearothermophilus* was used as a biological indicator. Based on internal test results, the sterilization process achieves a SAL between primary bag and overwrap of approx. 10^{-5} .

According to European Pharmacopoeia, chapter 5.1.1, sterility is the absence of viable microorganisms defined by a Sterility Assurance Level (SAL) less than or equal to 10^{-6} . For this reason, the surface of the primary bag Ecobag® IV cannot be formally claimed as sterile. Nevertheless, the biological indicator used for these studies (*G. stearothermophilus*), is an extremely heat-resistant germ which is not representative of the common flora of B. Braun production areas.

We herewith confirm that based on internal test results, the sterilization of Ecobag® IV achieves a significant microbial load reduction in the space between the primary bag and the overwrap. Therefore, opening an overwrapped Ecobag® IV in a controlled atmosphere area presents extremely low contamination risks.

B. Braun does not take any responsibility for an inappropriate storage or inappropriate use of our Infusion solutions.

Please do not hesitate to contact us if you have any further questions.

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Yours sincerely,

B. Braun Melsungen AG

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Dr. Bruno Legrand
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