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TO WHOM IT MAY CONCERN

An *in vitro* study was performed to determine the microbiological barrier properties of the topical skin adhesives Histoacryl® and Histoacryl® Flexible.

The assessment was carried out following the test procedure described in the publication "*In Vitro Assessment of Microbial Barrier Properties of Dermabond® Topical Skin Adhesive*" Shubhangi Bhende et al., Surgical Infections, Volume 3, Number 3, 2002.

The two topical skin adhesives were evaluated as a barrier to microbial penetration using a strike through test. Agar media containing pH sensitive dye was used. The dye changed color in the presence of acidic microbial metabolic products. Histoacryl® and Histoacryl® Flexible were applied to the agar surface to form uniformly thick films. A total of 480 single layered films (60 per test organism) were evaluated. A 10 µl aliquot of inoculum containing approx. 10⁶ CFU of one of the respective 8 microorganisms *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Escherichia coli*, *Pseudomonas aeruginosa*, *Enterococcus faecium*, *Brevundimonas diminuta*, *Aspergillus brasiliensis* and *Candida albicans* was applied to the surface of each film. Plates were incubated at 37 °C for 7 d and were observed for growth and color change during the incubation period.


Of the 480 test articles evaluated per test item, all test articles evaluable retained their integrity as microbial barriers for 7 d as measured by visual observation. For all positive controls evaluable microbial barrier was confirmed and all negative controls remained without microbial growth. Test units inoculated with *Aspergillus brasiliensis* were not evaluable due to overgrown agar plates indicating that *Aspergillus brasiliensis* is not applicable as test organism.

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Based on the results obtained in this *in vitro* study, it can be concluded that topical skin adhesives Histoacryl® and Histoacryl® Flexible provide an effective barrier to microbial penetration for 7 d as long as the adhesive film remains intact.

To complete this declaration, this document is approved and signed in Rubí, on November 5th, 2019.



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05.11.2019
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