



**Bemis Company, Inc.**  
Bemis Innovation Center  
2301 Industrial Drive  
P.O. Box 0669  
Neenah, WI 54957-0699  
U S A

October 1, 2015

To: Mr. Gergely Dömsödi  
Contest Kft  
gergely.domsodi@silicagel.hu

Re: Perfecseal® uncoated Tyvek®, including styles 1073B, 1059B, 2FS, & 1025B

Dear Mr. Dömsödi,

The following information is provided in good faith and to the best of our knowledge. We thank you for your interest in Bemis Healthcare Packaging products.

It is the responsibility of the buyer to test the package integrity, determine the suitability for marketplace, and use the products within the limits set forth herein:

| <u>Bemis Product Code</u> | <u>Packaged Product Type</u> | <u>Condition of Use</u> |
|---------------------------|------------------------------|-------------------------|
| uncoated Tyvek®           | medical device, dry          | room temp and below     |

**US:** The abovementioned products are manufactured in compliance with all applicable regulations set forth in title 21 of the Code of Federal Regulations §§ 174 – 189 as promulgated by the Food and Drug Administration. The raw materials have been reviewed and are compliant for the product type and condition of use listed above.

**EU:** The abovementioned products when used as intended meet the general requirements of European Regulation (EC) No 1935/2004 and the requirements of Regulation (EC) 2023/2006. The monomers and additives of the plastic components are compliant with Annex I of Regulation (EU) 10/2011, including amendments.

Please feel free to contact us if you require further information.

Sincerely,

Nancy K. Te Tai  
Regulatory Affairs Scientist  
Scientific & Regulatory Affairs  
Bemis Company, Inc.

cc: Deb O'Loughlin – Sales – BHP  
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