

**For submission to the competent
Authority of Malaysia**Contact: Patrice Nury
Email: Patrice.nury@bbraun.com
Internet: <http://www.bbraun.com>
Date: March 14, 2024**Letter of declaration****"Nutriflex® Omega Peri Novo Emulsion for Infusion"**
"Nutriflex® Lipid Special Novo Emulsion for Infusion"
"Nutriflex® Lipid Peri Novo Emulsion for Infusion"

We,

B. Braun Melsungen AG*Street Address:***Carl-Braun-Strasse 1****34 212 Melsungen****Germany***Postal Address:***34 209 Melsungen****Germany**

as responsible manufacturer hereby declares that the source of ingredients derived from animal origin such as

- Omega-3-acid triglycerides: Fish species of families like Engraulidae, Carangidae, Clupeidae, Osmeridae, Salmonidae and Scombridae. Esterification of marine oil with ethanol/sodium etoxide in ethanol solution followed by other processing steps

Or

- Egg phospholipids: Egg yolk from hens of German origin

cannot be stated and added on the Inner carton label as well on the Outer carton label because the size of the information is too large to be inserted.

The same goes for the in-use stability condition **"Upon mixing the admixtures are stable for 7 days between +2 °C to +8 °C plus 2 days at 25 °C"**.


Moreover, this information is not registered on any other labels and this for a question of harmonization within all countries.

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Yours sincerely,

B. Braun Melsungen AG represented by

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DocuSigned by:

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Dr. Yvonne Hupka
Team Leader GRA Operations Clinical Nutrition
Global Regulatory Affairs Pharma

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Dr. Patrice Nury
Global Regulatory Affairs Operations Manager

by Letter of Authorization (or alternative by a Power of Attorney)