

B. Braun Melsungen AG
Carl-Braun-Straße 1
34212 Melsungen,
Germany

To the competent Authority of Malaysia

Contact: Dr. Patrice Nury
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Internet: <http://www.bbraun.com>
Date: June 11, 2024

Letter of Declaration

We,

B. Braun Melsungen AG
Carl-Braun-Straße 1
34212 Melsungen
Germany

Postal Address:
34209 Melsungen
Germany

as a Responsible Manufacturer of the medicinal product

NUTRIFLEX® OMEGA PERI NOVO EMULSION FOR INFUSION

hereby offer supporting explanation for keeping the following statement in the SmPC / DfU – section 6.3 *Shelf life*:

After first opening (spiking of the infusion port)

The emulsion is to be used immediately after opening of the container.

Chemical and physicochemical in-use stability of the mixture of amino acids, glucose and fat was demonstrated for 7 days at 2–8 °C and an additional 2 days at 25 °C. However, this is not a priority **recommendation for the product's use**. It is not a recommendation for the regular product use to initially **prepare the chambers' mixture and store it in the conditions described in the in-use stability study** before its administration to the patient.

The ready-to-use product should be prepared at the time of the administration to the patient. If not used so, it is demonstrated that the mixture is stable for 7 days at 2–8 °C and an additional 2 days at 25 °C.

We hope that the explanation provided is satisfactory. We remain at your disposal.

Chairwoman of the Supervisory Board:
Anna Maria Braun, LL.M.

Executive Board:
Markus Strotmann
(Chairman)
Priv.-Doz. Dr. Stefan Ruppert
Jürgen Stihl

Corporate Office: Melsungen
Register Court:
Local Court Fritzlar
HRB 11 000
WEEE-Reg.-No. DE 42690900

Address:
B. Braun Melsungen AG
Carl-Braun-Straße 1
34212 Melsungen
Germany

Yours faithfully,

B. Braun Melsungen AG represented by

DocuSigned by:
Patrice Nury
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Dr. Patrice Nury
GRA Operations Manager
Global Regulatory Affairs CoE Pharma

DocuSigned by:
Dr. Bogdan Bumbacila
B8BF00B44137467...

Dr. Bogdan Bumbacila
GRA CMC Manager
Global Regulatory Affairs CoE Pharma

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