

Lægemiddelstyrelsen

Danish Medicines Agency

RH, Intensiv afd. Att.: Morten Hylander Møller
Blegdamsvej 9
2100 København Ø
Denmark

**‘Stress Ulcer Prophylaxis in the Intensive Care Unit (SUP-ICU)’,
Protokolnummer RH-ITA-006, EudraCT Number: 2015-000318-24.**

November 11, 2015

Case no: 2015110369

The Danish Medicines Agency acknowledge receipt of your letter dated October 22, 2015 concerning an amendment and the following enclosures:

Reference:

Lisa Sofie Wassini

T (dir.) 44889123

E kf@dkma.dk

- Clinical trial Application Form, signed by Morten Hylander Møller, dated October 22, 2015
- Protocol, version 3.0, dated October 20, 2015 (clean and track changes)

The Danish Medicines Agency hereby permit the implementation of the forwarded amendment.

An invoice for the amendment fee of DKK 1,728,- will be sent under separate cover.

Kind regards,



Sebastian Dyrby Johansen
On behalf of Lisa Sofie Wassini