



LÆGEMIDDELSTYRELSEN
DANISH MEDICINES AGENCY

Attn.: Anæstesiologisk afd. Nina Christine Andersen-Ranberg
Sjællands Universitetshospital, Køge
Lykkebækvej 1
4600 Køge
Danmark

05 December 2017
Case No.: 2017101527
Reference:
Mette Andersen
T +45 4488 91 23
E kf@dkma.dk

Agents Intervening against Delirium in Intensive Care Unit (AID-ICU), protocol no./code AID-ICU, EudraCT no. 2017-003829-15

The Danish Medicines Agency (DKMA) acknowledges receipt of your letter of 01 December 2017, in response to DKMA's conditional approval letter of 30 November 2017.

Receipt is also acknowledged of the following attachments to your above letter:

- Protocol, Version 3.6, 01 December 2017
- Protocol, Version 3.6, 01 December 2017 (protocol with revisions)
- EudraCT Form (pdf+xml), dated 01 December 2017

DKMA has no comments to your response, and the specified conditions are considered met.

Best Regards

Mette Andersen

Lægemedelstyrelsen
Axel Heides Gade 1
2300 København S
Denmark
T +45 44 88 95 95
E dkma@dkma.dk
LMST.DK