



TO WHOM IT MAY CONCERN

Date: 16-10-2020

Statement concerning manufacture of medicinal products in hospital pharmacies

Pursuant to the Danish Pharmacy Act (no. 801 of 12/06/2018) hospital pharmacies have an inherent permission to manufacture medicinal products. Therefore, hospital pharmacies do not hold a manufacturing authorization issued by the Danish Medicines Agency.

This statement is to confirm that the hospital pharmacy in the Capital Region of Denmark (Region H) is permitted to manufacture investigational medicinal products to be used in the clinical trial:

Goal directed fluid removal with furosemide in intensive care patients with fluid overload - A randomised, blinded, placebo-controlled trial (GODIF)

EudraCT no. 2019-004292-40

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