Union Format for a Good Distribution Practice Certificate (Medicinal Products for Human Use) EMA/171905/2012

Certificate No: DK GDP 00078816 1 /1

Danish Medicines Agency
Certificate No: DK GDP 00078816

## CERTIFICATE OF GDP COMPLIANCE OF A WHOLESALE DISTRIBUTOR

Issued following an inspection in accordance with Art. 111 of Directive 2001/83/EC

The competent authority of Denmark confirms the following:

The wholesale distributor: Combipack Danmark A/S

Site address: Stejlhøj 23, Kalundborg, 4400, Denmark

Has been inspected under the national inspection programme in connection with authorisation number 27303 in accordance with Art. 77 (1) of Directive 2001/83/ EC

From the knowledge gained during inspection of this wholesale distributor, the latest of which was conducted on 2016-06-01, it is considered that it complies with the Good Distribution Practice requirements laid down in Article 84 of Directive 2001/83/EC.

This certificate reflects the status of the premises at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than five years have elapsed since the date of that inspection. However this period of validity may be reduced using regulatory risk management principles, by an entry in the Restrictions or Clarifying Remarks field.

This certificate is valid only when presented with all pages.

The authenticity of this certificate may be verified in the Union database. If it does not appear please contact the issuing authority.

2016-09-07 Name and signature of the authorised person of the

Competent Authority of Denmark

Mr Thomas Vestergaard Pedersen

Danish Medicines Agency Tel: +45 2552 8157

tvp@dkma.dk

Details of the authorisation can be found in the Union Database.