



Federal Agency for Medicines and Health Products

Certificate No: BE/GDP/2016/005

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 Belgium confirms the following:

The wholesale distributor: IKRIS Pharma International SPRL

Site address: Rue Marcel de Brogniez 27/1, Rocleng-sur-Geer, 4690, Belgium

Has been inspected under the national inspection programme in connection with authorisation number 1876 H 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 2016-01-22, 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.

2016-06-06



Name and signature of the authorised person of the
Competent Authority of Belgium

Ethel MERTENS,

Head of Division Distribution
DG Inspection - FAMHP

Mr Xavier De Cuyper

Federal Agency for Medicines and Health Products

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