

CERTIFICATE OF GDP COMPLIANCE OF A DISTRIBUTOR OF ACTIVE SUBSTANCES FOR USE AS STARTING MATERIALS IN MEDICINAL PRODUCTS FOR HUMAN USE

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

The competent authority of France confirms the following:

The active substance distributor IMCD FRANCE SAS

Site address: Immeuble le Stadium CS 70005, 266 avenue du Président Wilson, SAINT DENIS, 93200, France

has been inspected in accordance with Art . 111(1) of Directive 2001/83/EC and in connection with registration no 2018-00700

From the knowledge gained during inspection of this active substance distributor, the latest of which was conducted on 2019-12-10, it is considered that it complies with the principles of Good Distribution Practice for active substances referred to in Article 47 of Directive 2001/83/EC.

This certificate reflects the status of the site 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.

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

Any restrictions or clarifying remarks related to the scope of this certificate(For All Users):

Signatory : Mrs Linda Gallais, head of starting materials inspection department --- The ANSM does not issue hard copies of good practices certificates

2020-01-29

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

Confidential

French National Agency for Medicines and Health Products
Safety
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