

Government of Upper Franconia

Certificate No: DE_BY_05_GDP_API_2022/53.2-2675.2-2-17-13

**CERTIFICATE OF GDP COMPLIANCE OF A DISTRIBUTOR OF ACTIVE
SUBSTANCES FOR USE AS STARTING MATERIALS**

Issued following an inspection in accordance with Art. 111(1) of Directive 2001/83/EC

The competent authority of Germany confirms the following:

The active substance distributor (API): CFM Oskar Tropitzsch GmbH

Site address: Adalbert-Zoellner-Strasse 1, Lorenzreuth, Marktredwitz, Bavaria, 95615

OMS Identifiers: (ORG-100035308 / LOC-100063945)

has been inspected in accordance with Art . 111(1) of Directive 2001/83/EC transposed in the following national legislation: Sect. 64 para 1 and 3 German Medicinal Product Act

Scope of certificate: Human Active Substances

From the knowledge gained during inspection of this active substance distributor, the latest of which was conducted on 2022-03-29, 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.

2022-12-28

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

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