

Regierungspresidium Tübingen, Leitstelle Arzneimittelüberwachung Baden-Württemberg

Certificate No: DE_BW_01_GDP_2022_0001_Takeda GmbH

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 Germany confirms the following:

The wholesale distributor: Takeda GmbH

Site address: Byk-Gulden-Strasse 2, Industriegebiet, Konstanz, Baden-Württemberg, 78467

Has been inspected under the national inspection programme in connection with authorisation number DE_BW_01_WDA_2021_0001_Takeda_GmbH 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 2020-10-07, 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.

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

Dispatch and transport of the medicinal products is carried out by the contracted logistics service providers (Trans-o-flex Logistik Service GmbH, Industriegebiet Sued A 12, 63755 Alzenau, Germany and Arvato Supply Chain Solution SE, Gottlieb-Daimler-Str. 1-2, 33428 Harsewinkel, Germany).

2022-07-06

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

Confidential

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Arzneimittelüberwachung Baden-Württemberg
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Details of the authorisation can be found in the Union Database.

EudraGMDP