

Bezirksregierung Koeln

CERTIFICATE NUMBER: **DE_NW_04_GMP_2022_0010**

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER ^{1,2}

Part 1

Issued following an inspection in accordance with
A111(5)-D2001/83/EC as amended

The competent authority of Germany confirms the following:

The manufacturer: **Universitaetsklinikum Bonn AöR**

Site address: **Venusberg-Campus 1, Venusberg, Bonn, North Rhine-Westphalia, 53127, Germany**

OMS Organisation Id. / OMS Location Id.: / **LOC-100052664**

Has been inspected under the national inspection programme in connection with manufacturing
authorisation no. **DE_NW_04_MIA_2022_0010** in accordance with Art. 40 of Directive 2001/83/EC.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted
on **2021-07-27**, it is considered that it complies with:

- The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC³

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and
should not be relied upon to reflect the compliance status if more than three years have elapsed since the date
of that inspection. However, this period of validity may be reduced or extended using regulatory risk
management principles by an entry in the Restrictions or Clarifying remarks field. Updates to restrictions or
clarifying remarks can be identified through the EudraGMDP website (<http://eudragmdp.ema.europa.eu/>).

This certificate is valid only when presented with all pages and both Parts 1 and 2.

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

¹The certificate referred to in paragraph Art. 111(5) of Directive 2001/83/EC is also applicable to importers.

²Guidance on the interpretation of this template can be found in the Interpretation of the Union format for GMP certificate.

³These requirements fulfil the GMP recommendations of WHO.

Part 2

Human Medicinal Products	
1 MANUFACTURING OPERATIONS	
1.3	Biological medicinal products (list of product types)
	<i>1.3.1 Biological medicinal products (list of product types)</i> 1.3.1.1 Blood products
	<i>1.3.2 Batch Certification (list of product types)</i> 1.3.2.1 Blood products
1.4	Other products or manufacturing activity
	<i>1.4.1 Manufacture of</i> 1.4.1.3 Other: - Human plasma for fractionation from apheresis and/or whole blood - Lymphocyte concentrates from apheresis (also cryopreserved) as starting material for the production of CAR-T cell therapeutics for autologous use and as starting material for the production of investigational medicinal products as part of the clinical trials: - EudraCT-No.: 2019-003384-21 - EudraCT-No.: 2019-001417-17 - EudraCT-No.: 2019-002370-31(en)
1.6	Quality control testing
	<i>1.6.3 Chemical/Physical</i>
2 IMPORTATION OF MEDICINAL PRODUCTS	
2.2	Batch certification of imported medicinal products
	<i>2.2.3 Biological medicinal products</i> 2.2.3.1 Blood products

Clarifying remarks (for public users)

The authorisation includes only the premises of the Institute for Experimental Hematology and Transfusion Medicine (IHT) of the University Hospital Bonn, Venusberg-Campus 1, Building 43, 53127 Bonn The authorisation referring to 1.3.1.1 includes: - red blood cell concentrates - allogeneic blood preparations from whole blood, also irradiated and/or washed - platelet concentrates - allogeneic blood preparations from whole blood and/or apheresis, also pooled, irradiated and/or washed - fresh frozen plasma - allogeneic blood preparations from whole blood and/or apheresis also stored in quarantine, also cryoprecipitate-depleted - peripheral blood stem cells - allogeneic blood preparations also cryopreserved - other products - allogeneic blood preparations donor-lymphocyte concentrates from apheresis also cryopreserved - Mixed blood preserves from blood components - red blood cell concentrates - autologous blood preparations from whole blood also leukocyte-dep (text missing)

2022-04-05

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

Confidential
Bezirksregierung Köln
Tel: *Confidential*
Fax: *Confidential*

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