

Bezirksregierung Koeln

CERTIFICATE NUMBER: **DE_NW_04_GMP_2024_0046**

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

Part 1

Issued following an inspection in accordance with
Art. 15 of Directive 2001/20/EC as amended

The competent authority of Germany confirms the following:

The manufacturer: **Miltenyi Biotec B.V. & Co. KG**

Site address: **Friedrich-Ebert-Strasse 68, Moitzfeld, Bergisch Gladbach, 51429**

OMS Organisation Id. / OMS Location Id.: **ORG-100045922 / LOC-100075732**

Has been inspected under the national inspection programme in connection with manufacturing
authorisation no. **DE_NW_04_MIA_2024_0028** in accordance with Art. 13 of Directive 2001/20/EC.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted
on **2023-05-23**, it is considered that it complies with::

- The principles and guidelines of Good Manufacturing Practice laid down in Directive (EU) 2017/1572
and/or Commission Delegated Regulation (EU) 2017/1569, as reflected by the product categories stated in
Part 2.³

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. 15 of Directive 2001/20/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 Investigational Medicinal Products
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1 MANUFACTURING OPERATIONS	
1.3	Biological medicinal products (list of product types)
	<i>1.3.1 Biological medicinal products (list of product types)</i> 1.3.1.4 Gene therapy products
	<i>1.3.2 Batch Certification (list of product types)</i> 1.3.2.4 Gene therapy products
1.5	Packaging
	<i>1.5.1 Primary Packaging</i> 1.5.1.6 Liquids for internal use
	<i>1.5.2 Secondary packaging</i>
1.6	Quality control testing
	<i>1.6.1 Microbiological: sterility</i> <i>1.6.3 Chemical/Physical</i> <i>1.6.4 Biological</i>

2 IMPORTATION OF MEDICINAL PRODUCTS	
2.2	Batch certification of imported medicinal products
	<i>2.2.3 Biological medicinal products</i> 2.2.3.4 Gene therapy products
2.3	Other importation activities
	<i>2.3.4 Other: The authorisation includes the import of autologous leukapheresates as starting material for the production of T-cell preparations for investigational medicinal products.(en)</i>

Clarifying remarks (for public users)

To 1.3.1.4 The authorisation is restricted to: - autologous CAR-T cell preparations including transduction by using a lentiviral vector: MB-CART19.1, MB-CART20.1 and MB-CART2019.1 (also cryoconserved), MB-CART2219.1 - autologous T cell preparations ADP-001, GSK3845097 and GSK3901961. The apheresis product requires a washing, cryoconservation and thawing step before transduction with a lentiviral vector and final cryoconservation. The cell preparations are manufactured by using the CliniMACS Prodigy(R). To 1.6 The authorisation also includes the following quality control testings: - Multiparametric MACSQuant analysis (Flow cytometry) - Quantitative duplex PCR for determination of vector copy number - Microbiological testing (microbiological examination of cell-based preparations acc. to EP 2.6.27, endotoxins acc. to EP 2.6.14) - Biological testing (testing for mycoplasmas acc. to EP 2.6.7) The company Rhenus Archiv Services GmbH, Hornpottweg 9 in 51375 (text missing)

2024-11-21

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

Confidential
Bezirksregierung Koeln
Tel: ***Confidential***
Fax: ***Confidential***

Manufacturer/Importer Authorisation^{1, 2}

1. Authorisation Number DE_NW_04_MIA_2024_0028
2. Name of authorisation holder Miltenyi Biotec B.V. & Co. KG (ORG-100045922 / LOC-100075732)
3. Address(es) of manufacturing site(s) Miltenyi Biotec B.V. & Co. KG (ORG-100045922 / LOC-100075732), Friedrich-Ebert-Strasse 68, Moitzfeld, Bergisch Gladbach, 51429, Germany
- 3.a Additional details on units inspected of manufacturing site(s) address(es)
4. Legally registered address of authorisation holder Friedrich-Ebert-Strasse 68, Moitzfeld, Bergisch Gladbach, 51429, Germany
- 4.a Additional details on units inspected of legally registered address
5. Scope of authorisation and dosage forms² ANNEX 1 and/ or ANNEX 2
6. Legal Basis of authorisation Art. 61 of Regulation (EU) No 536/2014
7. Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation confidential
8. Signature
9. Date 2024-11-21
10. Annexes attached Annex 1 and/or Annex 2
Optional Annexes as required:
Annex 3(Addresses of Contract Manufacturing Site(s))
Annex 4(Addresses of Contract laboratories)
Annex 5(Name of Qualified Person)
Annex 6(Name of responsible persons)
Annex 7(Date of inspection on which authorisation granted, scope of last inspection)
Annex 8(Manufactured/ imported products authorised)³

¹The authorisation referred to in paragraph 40(1) of Directive 2001/83/EC as amended and Article 88(1) of Regulation (EU) 2019/6, shall also be required for imports coming from third countries into a Member State.

²Guidance on the interpretation of this template can be found in the Interpretation of the Union format for Manufacturer/Importer Authorisation.

³The Competent Authority is responsible for the appropriate linking of the authorisation with the manufacturer's application (Article 42(3) of Directive 2001/83/EC as amended and Article 90(3) of Regulation (EU) 2019/6).

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SCOPE OF AUTHORISATION

ANNEX 2

Name and address of the site : Miltenyi Biotec B.V. & Co. KG, Friedrich-Ebert-Strasse 68,
Moitzfeld, Bergisch Gladbach, 51429, Germany

Additional Details:

Human Investigational Medicinal Products
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Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)

IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)

Part 1 - MANUFACTURING OPERATIONS

1.3	Biological medicinal products (list of product types)
	<i>1.3.1 Biological medicinal products (list of product types)</i> 1.3.1.4 Gene therapy products
	<i>1.3.2 Batch Certification (list of product types)</i> 1.3.2.4 Gene therapy products
1.5	Packaging
	<i>1.5.1 Primary Packaging</i> 1.5.1.6 Liquids for internal use
	<i>1.5.2 Secondary packaging</i>
1.6	Quality control testing
	1.6.1 Microbiological: sterility 1.6.3 Chemical/Physical 1.6.4 Biological

Any restrictions or clarifying remarks related to the scope of these Manufacturing operations (for Public users)

To 1.3.1.4 The authorisation is restricted to: - autologous CAR-T cell preparations including transduction by using a lentiviral vector: MB-CART19.1, MB-CART20.1 and MB-CART2019.1 (also cryoconserved), MB-CART2219.1 - autologous T cell preparations ADP-001, GSK3845097 and GSK3901961. The apheresis product requires a washing, cryoconservation and thawing step before transduction with a lentiviral vector and final cryoconservation. The cell preparations are manufactured by using the CliniMACS Prodigy(R). To 1.6 The authorisation also includes the following quality control testings: - Multiparametric MACSQuant analysis (Flow cytometry) - Quantitative duplex PCR for determination of vector copy number - Microbiological testing (microbiological examination of cell-based preparations acc. to EP 2.6.27, endotoxins acc. to EP 2.6.14) - Biological testing (testing for mycoplasmas acc. to EP 2.6.7) The company Rhenus Archiv

Services GmbH, Hornpottweg 9 in 51375 L (text missing)

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS	
2.2	Batch certification of imported medicinal products
	2.2.3 <i>Biological medicinal products</i> 2.2.3.4 Gene therapy products
2.3	Other importation activities
	2.3.4 Other: The authorisation includes the import of autologous leukapheresates as starting material for the production of T-cell preparations for investigational medicinal products.(en)

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