



Health and Youth Care Inspectorate – Pharmaceutical Products

CERTIFICATE NUMBER: *NL/H 22/2043618*

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

Part 1

Issued following an inspection in accordance with :

Art. 111(5) of Directive 2001/83/EC as amended

The competent authority of Netherlands confirms the following:

The manufacturer: *Dentech B.V.*

Site address: *Heliumstraat 8, Zoetermeer, 2718 SL, Netherlands*

OMS Organisation Id. / OMS Location Id.: *ORG-100007192 / LOC-100011761*

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. *6476 F* in accordance with Art. 40 of Directive 2001/83/EC transposed in the following national legislation:

Art. 100 of the Medicines Act

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **2022-09-22**, it is considered that it complies with:

- The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC 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. 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, 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 Help menu of EudraGMDP database.

³These requirements fulfil the GMP recommendations of WHO.



Part 2

Human Medicinal Products

1 MANUFACTURING OPERATIONS	
1.2	Non-sterile products
	1.2.1 <i>Non-sterile products (processing operations for the following dosage forms)</i> 1.2.1.5 Liquids for external use
	1.2.2 <i>Batch certification</i>
1.5	Packaging
	1.5.1 <i>Primary Packaging</i> 1.5.1.5 Liquids for external use
	1.5.2 <i>Secondary packaging</i>

Any restrictions related to the scope of this certificate:

Activity 1.2.1.5: both finished products and intermediate products.

Clarifying remarks (for public users)

Activity 1.2.1.5: both finished products and intermediate products.

2023-01-30

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

Christianne Reijnders
Tel: +31 88 1205000
Fax: +31 88 1205001