Awtorità dwar il-Mediċini

CERTIFICATE NUMBER: ***MT/053HM/2022***

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 Malta confirms the following:
The manufacturer: ***Panaxia Cannabis Israel Ltd.***
Site address: ***1 Bat Sheva, Lod, 7120101, Israel***
OMS Organisation Id. / OMS Location Id.: ***ORG-100044749*** / ***LOC-100073964***
DUNS Number: ***53-188-4806***

Other
Has been inspected in accordance with Art 4 (2d) of the Production of Cannabis for Medicinal and Research Purposes Act (Chapter 578 of the Laws of Malta)

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2022-03-24*** , it is considered that it complies with

- The principles and guidelines of Good Manufacturing Practice laid down in Directive (EU) 2017/1572 and Commission Delegated Regulation (EU) 2017/1569 [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.

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[1] *The 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.*

[2] *Guidance on the interpretation of this template can be found in the Help menu of EudraGMDP database.*

[3] *These requirements fulfil the GMP recommendations of WHO.*

Part 2

Human Medicinal Products

1 MANUFACTURING OPERATIONS	
1.2	**Non-sterile products**
	1.2.1 Non-sterile products (processing operations for the following dosage forms) 1.2.1.6 Liquids for internal use
1.4	**Other products or manufacturing activity**
	1.4.1 Manufacture of 1.4.1.1 Herbal products
1.6	**Quality control testing**
	1.6.3 Chemical/Physical

Clarifying remarks (for public users)

This certificate is limited in scope to bulk cannabis product intermediates (inflorescence in bulk and cannabis extracts in bulk including cannabis native extracts and standardized cannabis extracts) for medicinal use, and including the primary packaging of this same bulk. In accordance with national legislation, the site manufacturing cannabis products for medicinal use has to comply with EU-GMP requirements for medicinal products. This certificate has been re-issued to clarify further this clarifying remark and to correct the postcode of the site address.

2022-11-01

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

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Confidential
Medicines Authority
Tel:***Confidential***
Fax:***Confidential***