



Certificate No: **GMP 283/1**

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

Issued following an inspection in accordance with the requirements of Good Manufacturing Practice, of the Israeli laws and regulations (Pharmacist Regulations [Good Manufacturing Practice for Medicinal Products] 2008)

and

Issued under the provisions of the Conformity Assessment and Acceptance of Industrial Products (CAA) Agreement between the European Union and Israel

The competent authority of Israel confirms the following:

The manufacturer IGL Medical

Site address 2 Tut St., Zikhron Yaacov, 3092896, Israel

Has been inspected under the Israeli inspection programme, in connection with manufacturing authorization no. **MIA 283**, in accordance with the above mentioned laws and regulations

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **7 January 2026**, it is considered that it complies with the Good Manufacturing Practice requirements referred to in the Conformity Assessment and Acceptance of Industrial Products (CAA) Agreement between the European Union and Israel and the above mentioned Israeli laws and regulations (*).

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 EudraGMP.

If it does not appear, please contact the issuing authority.

(*) these requirements fulfill the GMP recommendations of WHO



15 -01- 2026

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GMP 283/1

page 1 of 2



Part 2

HUMAN MEDICINAL PRODUCTS

1. MANUFACTURING OPERATIONS - MEDICINAL PRODUCTS

performed by contract manufacturers

1.5 Packaging (of imported products)

1.5.2 Secondary packing (limited to customization, relabeling & adding/replacing of leaflets)
relabeling of primary containers that are not made of metal or glass should be pre-approved by the GMP Inspectorate when the products is not solid

2. IMPORTATION OF MEDICINAL PRODUCTS

2.2 Batch certification of imported medicinal products

2.2.1 Sterile Products

2.2.1.1 Aseptically prepared

2.2.1.2 Terminally sterilized

2.3 Other importation activities

2.3.1 Site of physical importation : *contract manufacturers' sites*

Any restrictions or clarifying remarks related to the scope of this certificate

The site is an administrative release site (QA/QP activities) of a local importer. The products are imported, stored, customized (when needed) and distributed by contract manufacturers.

Name and signature of the authorized person of the Competent Authority of Israel

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GMP 283/1

page 2 of 2