

FOR INFORMATION (not signed)

14 January 2026

אישור יצרן / יבואן תכשירים רפואיים
MANUFACTURER'S / IMPORTER'S AUTHORIZATION

Authorization number	מספר האישור
MIA 283/2026/A	
Name of authorization holder	שם בעל האישור
IGL Medical	אי ג'י אל מדיקל
Address of site	כתובת האתר
2 Tut St., Zikhron Yaacov, 3092896, Israel	רחוב תות 2, זכרון יעקב, 3092896
Legally registered address of authorization holder	כתובת בעל האישור
2 Tut St., Zikhron Yaacov, 3092896, Israel	רח' תות 2, זכרון יעקב, 3092896
Scope of authorization and dosage forms	תחומי האישור וצורות המינון
See Annexes 1, 2	ראה נספחים 1, 2
Legal basis of authorization	הבסיס החוקי לאישור
Pharmacist Regulations [Good Manufacturing Practice] 2008	תקנות הרוקחים [תנאי ייצור נאותים] תשס"ח
Responsible officer of Israeli Ministry Of Health granting the authorization	בעל התפקיד ברשות האחראי למתן האישור
Michael Carmi, Pharmacist GMP inspector	מיכאל כרמי, רוקח רכז ארצית בקרת מפעלים
Signature, stamp and date	התימה. הותמת ותאריך
e-mail: michael.carmi@moh.gov.il phone: office 972-2-6551795, cell 972-50-6242452	

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Annexes attached	רשימת הנספחים המצורפים
Annex 1 and/or Annex 2	נספח 1 ו/או נספח 2
Optional Annexes	רשימת נספחי רשות
Annex 3 – Contract Manufacturers	נספח 3 – אתרי ייצור בקבלנות משנה
Annex 4 – Contract Laboratories	נספח 4 – מעבדות בקבלנות משנה
Annex 5 – Qualified Person(s)	נספח 5 – הרוקחים האחראיים
Annex 6 - Responsible persons(s)	נספח 6 – העובדים האחראיים לאיכות ולייצור
Annex 7 – Date of inspection on which authorization granted, scope of last inspection	נספח 7 – תאריך הביקורת שעל בסיסה ניתן האישור, היקף הביקורת האחרונה
Annex 8 – Manufactured/imported products authorized	נספח 8 – רשימת התכשירים הכלולים באישור
<u>Clarifying remarks related to this authorization</u> The site is a local administrative release site (performing QA/QP activities) of an international manufacturer. the imported products are stored, customized (when needed) and distributed by contract manufacturers.	<u>מידע נוסף בנוגע לאישור זה</u> האתר משמש כאתר שחרור אדמיניסטרטיבי של תכשירי יבוא (אתר QA/QP). התכשירים מאוחסנים, עוברים התאמות אריזה (כמידת הצורך) ומופצים ע"י קבלני משנה לוגיסטיים.

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SCOPE OF AUTHORIZATION : ANNEX 1 – MEDICINAL PRODUCTS

Name and address of the site **IGL Medical**
2 Tut St., Zikhron Yaacov, 3092896, Israel

☒ Human Medicinal Products

AUTHORIZED OPERATIONS

- ☒ Manufacturing Operations (according to part 1)
☒ Importation of Medicinal Products (according to part 2)

Part 1 – MANUFACTURING OPERATIONS
performed by contract manufacturers

1.5	Packaging (<i>of imported medicinal products</i>)
	1.5.2 Secondary packing (<i>limited to customization, relabeling & adding/replacing of leaflets</i>) <i>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</i>

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

2.2	Batch certification of imported medicinal product
	2.2.1 Sterile Products 2.2.1.1 Aseptically prepared 2.2.1.2 Terminally sterilized
	2.2.2 Non- sterile products
2.3	Other importation activities
	2.3.1 Site of physical importation : <i>contract manufacturers' sites</i>

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SCOPE OF AUTHORIZATION : ANNEX 2 - INVESTIGATIONAL PRODUCTS

Name and address of the site IGL Medical
2 Tut St., Zikhron Yaacov, 3092896, Israel

Not applicable

ANNEX 3

Contract Manufacturers

for importing, holding and distributing

Drugstore. Net Ltd.
10 Zvi Bergman street, Petach Tikva, Israel

for importing, holding, customizing (when needed) and distributing

Chemipal Ltd.
44 Giborey Israel St., Yehuda House, Sapir Park, Netanya, Israel

for importing and holding

Chemipal Ltd.
7 HaTe'ena St., Mevo Carmel Ind. Park, Israel

ANNEX 4

Contract Laboratories

None

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ANNEX 5

Qualified Person(s)

Hagar Sa'ar Sivan, Pharmacist

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ANNEX 6

Person(s) responsible for quality control

Yaron Ziv - Quality Assurance Manager

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ANNEX 7

Date of inspections on which authorization was granted

7 January 2026 : First inspection of a new importer

Scope of last inspection

GMP general inspection

The site conforms to the requirements of Good Manufacturing Practice, as recommended by the World Health Organization, and complies to the national laws and regulations (Pharmacist Regulations [Good Manufacturing Practice for Medicinal Products] 2008).

ANNEX 8

Products authorized to be manufactured/imported

The site is an administrative release site (QA/QP activities) of a local affiliate of an international manufacturer.

The products are stored, customized (when needed) and distributed by contract manufacturers

Manufacturing activity

The customization (when needed) is performed by contract manufacturers

Importation activity

The manufacturer is an importer of medicinal products

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Products authorized to be released/recertified by the Qualified Person(s)

- Imported products that are registered by the following Marketing Authorization Holder :

IGL Medical

- Non- registered imported products