



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

Authorization nu	מספר האישור
MIA 36/2022/A	
Name of authorization holder Medison Pharma Ltd.	שם בעל האישור מדיסון פארמה בע"מ
Address of site (QA/QP release site) 10 HaShiloach St., Petach Tikva, 4951143, Israel	כתובת האתר (אתר שחרור) רח' השילוח 10, פתח תקווה 4951143
Legally registered address of authorization holder As written above	כתובת בעל האישור כרשום לעיל
Scope of authorization and dosage forms See Annexes 1, 2	תחומי האישור וצורות המינון ראהנספחים 1, 2
Legal basis of authorization Pharmacist Regulations [Good Manufacturing Practice] 2008	הבסיס החוקי לאישור תקנות הרוקחים [תנאי ייצור נאותים] תשס"ח
Responsible officer of Israeli Ministry Of Health granting the authorization Michael Carmi, Pharmacist GMP inspector	בעל התפקיד ברשות האחראי למתן האישור מיכאל כרמי, רוקח רכז ארצי בקרת מפעלים
Signature, stamp and date <i>Email: michael.carmi@moh.gov.il Phone: office 972 -2-6551795, cell 972-50-6242452</i>	חתימה, הותמת ותאריך  18-05-2022

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SCOPE OF AUTHORIZATION

ANNEX 1 - MEDICINAL PRODUCTS

Name and address of site **Medison Pharma Ltd.**
10 HaShiloach St., Petach Tikva, 4951143, Israel

<input checked="" type="checkbox"/> Human Medicinal Products
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AUTHORIZED OPERATIONS
<input checked="" type="checkbox"/> Manufacturing Operations (according to part 1)
<input checked="" type="checkbox"/> Importation of Medicinal Products (according to part 2)

Part 1 – MANUFACTURING OPERATIONS	
1.5	Packaging only (<i>performed by contract manufacturers – see Annex 3</i>)
	1.5.2 Secondary packing <ul style="list-style-type: none"> • <i>relabeling of primary containers (glass containers only)</i> • <i>customization (secondary relabeling and leaflets adding/replacing)</i>

Part 2 – IMPORTATION OF MEDICINAL PRODUCTS	
2.2	Batch certification of imported medicinal products
	2.2.1 Sterile Products <ul style="list-style-type: none"> 2.2.1.1 Aseptically prepared 2.2.1.2 Terminally sterilized
	2.2.2 Non-sterile products
	2.2.3 Biological medicinal products
	2.2.3.1 Blood products (<i>containing Albumin</i>)
	2.2.3.2 Immunological products
	2.2.3.5 Biotechnology products
2.3	Other importation activities <ul style="list-style-type: none"> 2.3.4 -Radiopharmaceuticals/Radionuclide generators

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18-05-2022





SCOPE OF AUTHORIZATION

ANNEX 2 - INVESTIGATIONAL MEDICINAL PRODUCTS

Name and address of site **Medison Pharma Ltd.**
10 HaShiloach St., Petach Tikva, 4951143, Israel

Not Relevant

