衛生福利部第一等級醫療器材許可證

衛部醫器製壹字第 009155 號

中文品名： 阿波羅分析判讀儀(未滅菌)

英文品名： Apollo iaX2101 Intelligent Analyzer (Non-sterile)

類　　別： 第 A 類：臨床化學及臨床毒理學

醫療器材商名稱： 阿波羅研發科技股份有限公司

規格或型號： 空白

製造業者名稱及地址： 阿波羅研發科技股份有限公司委託恆河醫電股份有限公司(新北市五股區五權路 23 號 1 樓、4 樓)製造

效能、用途或適應症： 限醫療器材分類分級管理辦法「臨床使用的色度計、光度計或分光光度計(A.2300)」第一等級鑑別範圍。

本品不包括校正品(Calibrator)、標準品(Standard)及含有人類或動物血清之品管液(Control)。

前項醫療器材經本部審核與醫療器材管理法之規定相符應發給許可證以資證明

衛生福利部部長

陳時中

發證日期　110　年　06　月　29　日

有效日期　115　年　06　月　29　日

核准展延至	年　月　日	年　月　日	年　月　日	年　月　日
文號				

MK 017713

中 華 民 國 衛 生 福 利 部

MINISTRY OF HEALTH AND WELFARE, REPUBLIC OF CHINA
(TAIWAN)

Date: JUL 14 2021 No: 083107

證 明 書

Certificate

茲證明下述醫療器材製造廠符合衛生福利部醫療器材管理法規定，
亦符合衛生福利部施行之醫療器材品質管理系統準則，
其所產製之醫療器材，准予銷售及輸出。
It is hereby certified that the medical device manufacturer as described below is in compliance with the provisions of Medical Devices Act governed by the Ministry of Health and Welfare, Republic of China (Taiwan), and also in compliance with Regulations Governing Medical Device Quality Management System enforced by the Ministry of Health and Welfare, Republic of China (Taiwan). The medical devices it has manufactured may be freely sold and exported.

製造廠名稱及地址：
阿波羅研發科技股份有限公司（新北市汐止區新台五路 1 段 75 號 18 樓之 1）委託 恆河醫電股份有限公司（新北市五股區五權路 23 號 1 樓、4 樓）製造

Manufacturer and Manufacturing Plant Location：
Manufactured By Amedifact Co., Ltd. (1F、4F, No.23, Wuquan Rd., Wugu Dist., New Taipei City, Taiwan) For Apollo BioTech Co., Ltd. (18F-1, No. 75, Sec. 1, Xintai 5th Rd., Xizhi Dist., New Taipei City 221, Taiwan)

產品列表：見附件
Products List：See Attached List.

Signed by Shou-Mei Wu

Director General
Food and Drug Administration

for Shih-Chung Chen, D.D.S.
Minister
Ministry of Health and Welfare,
Republic of China (Taiwan)

許可證字號/登錄字號 **License Number / Listing Number**	醫療器材名稱 **Device Name**	規格（型號） **Model (Type)**	有效日期 **Expiry Date**
衛部醫器製壹字第 009155 號 MOHW-MD-(I)-No.009155	阿波羅分析判讀儀(未滅菌) Apollo iaX2101 Intelligent Analyzer (Non-sterile)	All Models	Jun. 29, 2026

End of Products List.

EMERGO

Product Listing Appendix | UK

Device Family Name	Device Trade Name	Classification	Applicable Regulation/ Directives
Assaya iaX-2101	Assaya intelligent analyzer eXpress	IVDR ☒ Class A	☒ IVDR ☒ RoHS ☒ EMC

Medicines & Healthcare products
Regulatory Agency

Medicines & Healthcare products
Regulatory Agency

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

+44 (0) 20 3080 6000
gov.uk/mhra

Emergo Consulting (UK) Limited
Compass House, Vision Park Histon
c/o Cr360 – UL International
Cambridge
CB24 9BZ
England, United Kingdom

16 September 2022

Dear **Karen Hill**

We are pleased to confirm that the application to register or update an existing registration for the following manufacturer, which you submitted on **15 September 2022** has been reviewed:

Application reference: **2022091501277316**

Manufacturer organisation: **Apollo Biotech co., ltd.**
Address:
18F-1 No. 75 Xintai 5th Road
New Taipei
New Taipei City
22101
Taiwan

Manufacturer registration status: **Registered**

Device(s):

GMDN Code & Term	Status	Comment
61302 - Clinical laboratory analyser/instrument control unit IVD	Registered	

Please note this letter does not represent any form of accreditation, certification or approval by the UK Competent Authority.

If you stop placing devices on the market or if you are not complying with the Regulations, you should inform us so that we can amend our records. You should be aware that it is an offence to place on the market UKCA or CE marked devices that do not comply with the regulations.

Please inform us of the following chargeable changes:

1. **company/organisation information e.g. name and address**
2. **additional devices (GMDN code or term)**

Please also use the Devices Online Registration Database (DORS) to tell us of the following changes e.g. removal/ discontinuation of a device (GMDN) or product from your registration record, change of contact person, telephone number and/or email address, for which payment of our statutory fee does not apply.

Please note that the name and address of manufacturer, UK Responsible Person or Authorised Representative (Northern Ireland only) and devices that have been registered will be published on our Public Access Registration Database (PARD). In vitro diagnostic medical devices registered as undergoing performance evaluation study are not published on this database.

The account number for your company/organisation is **0000026022.**

Please do not respond directly to this email address. The originating email account is not monitored.

Yours sincerely,

Ngozi Onyeukwu
Device registrations service
Devices division
Medicines and Healthcare products Regulatory Agency

- My cases
- Notify medical devices
- Change products
- Apply for certificate of free sale
- Find products

Notify medical devices and IVDs

General data

NOTIS number	20221858
Date of receipt	3/25/2022
Status	Received

Client details

Name	Emergo Europe B.V.
Contact person concerning this notification	Hogendorf, dhr. H.

Manufacturer details

Authorised representative of manufacturer	Apollo BioTech co., ltd.
Address	18F-1 No 75 Xintai 5th Road, Xizhi
Zipcode	
City	22101 New Taipei City
Country	TAIWAN (PROVINCE OF CHINA)

Products

Brand name *	Group name	Article number(s)	Model(s)	Class	Status
Assaya intelligent an...	Assaya iaX-2101			IVDR A	NOT

Documents

Date	File	Title
3/25/2022	20221858-0001.pdf	Declaration of Conformity
3/25/2022	20221858-0002.pdf	Product information
3/25/2022	20221858-0003.pdf	Product information

Add document

Consultas

ANVISA - Agência Nacional de Vigilância Sanitária

Detalhes do Produto	
Nome da Empresa	VYTTRA DIAGNOSTICOS IMPORTACAO E EXPORTACAO S.A.
CNPJ	00.904.728/0012-09
Autorização	8.16.926-1
Produto	proxima iaX - Analisador Inteligente

Modelo Produto Médico
2101

Tipo de Arquivo	Arquivos	Expediente, data e hora de inclusão
INSTRUÇÕES DE USO OU MANUAL DO USUÁRIO DO PRODUTO	Proxima IaX- Analisador Inteligente_2101 - 81692610238.pdf	3973275211 - 08/10/2021 09:29:06

Nome Técnico	Instrumento destinado a imunoensaios
Registro	81692610238
Processo	25351414466202172
Fabricante Legal	APOLLO BIOTECH CO. LTD
Classificação de Risco	II - Classe II: produtos de médio risco ao indivíduo e ou baixo risco à saúde pública
Vencimento do Registro	*[sem dados cadastrados]*

Device Details

Generic Name	Brand Name	Model Detail	Device Class	File no
Intelligent Analyzer iaX-2101	Apollo eXpress Intelligent Analyzer iaX-2101		Class A	La-med-Farid-HR/M/MD/004231

Establishment Registration & Device Listing

1 result found for **Establishment Registration or Business Trade Name :** *Apollo biotech*

New Search

Establishment Name	Registration Number	Current Registration Yr
APOLLO BIOTECH CO., LTD. TAIWAN	3017877290	2024
• Colorimeter, Photometer, Spectrophotometer For Clinical Use - Apollo BioTech IaX-2101; Assaya IaX-2101; Assaya Intelligent Analyzer EXpress-2101		Foreign Exporter; Specification Developer

Can't find what you're looking for? Try a new search

Page Last Updated: 12/11/2023

Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Русский | العربية | Kreyòl Ayisyen | Français | Polski | Português | Italiano | Deutsch | 日本語 | فارسی | English

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

Establishment Registration & Device Listing

New Search | Back To Search Results

Establishment:
APOLLO BIOTECH CO., LTD.
18F-1 No. 75 Xintai 5th Road
Xizhi 22101
New Taipei City, TW 22101
Registration Number: 3017877290
FEI Number*: 3017877290
Status: Active
Date Of Registration Status: 2024

Owner/Operator:
Apollo BioTech Co., Ltd.
18F-1 No. 75 Xintai 5th Road
Xizhi 22101
New Taipei City, TW 22101
Owner/Operator Number: 10082148

Official Correspondent:
Abri-Elle Sivertsen
18F-1 No. 75 Xintai 5th Road
Xizhi 22101
New Taipei City, TW 22101
Phone: 886-2271-88360

US Agent:
Abri-Elle Sivertsen
641 W Johns Rd
Lilburn, GA US 30047
Phone: 678 2341775 Ext
Email: Ae@Apollo.Bio

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

Establishment Registration & Device Listing

New Search | Back To Search Results

Proprietary Name:	Apollo BioTech iaX-2101; assaya iaX-2101; assaya intelligent analyzer eXpress-2101
Classification Name:	COLORIMETER, PHOTOMETER, SPECTROPHOTOMETER FOR CLINICAL USE
Product Code:	JJQ
Device Class:	1
Regulation Number:	862.2300
Medical Specialty:	Clinical Chemistry
Registered Establishment Name:	APOLLO BIOTECH CO., LTD.
Registered Establishment Number:	3017877290
Owner/Operator:	Apollo BioTech co., ltd.
Owner/Operator Number:	10082148
Establishment Operations:	Foreign Exporter; Specification Developer

Page Last Updated: 12/11/2023

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Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Русский | العربية | Kreyòl Ayisyen | Français | Polski | Português | Italiano | Deutsch | 日本語 | فارسی | English

CE

Worldwide Testing Services (Taiwan) Co., Ltd.

ACCREDITED TEST HOUSE

CERTIFICATION OF TESTING

Under EU EMC - DIRECTIVE 2014/30/EU -

This certifies that the following designated product

Apollo eXpress Intelligent Analyzer
Model No.: iaX-2101

(Product identification)

Has been tested in accordance to essential protection requirements of Council Directive 2014/30/EU and found the test results indeed meet the limitation of the relevant test standard(s) listed below:

EN 60601-1-2 (2015), IEC 60601-1-2 (2014-02)
CISPR 11 (2015+A2: 2019),
ICE/EN61000-3-2 (2020)/-3 (2013/A1:2017)
(IEC/EN61000-4-2 (2009)/-3 (2020)/-4 (2012)/-5 (2014+A1:2017)/-6 (2014)/
-8 (2010)/-11 (2020))

(Identification of regulations / standards)

This certificate is issued for

Apollo BioTech co., ltd.
18F-1 No. 75 Xintai 5th Road, Xizhi 22101 New Taipei City,
Taiwan

(Name / Address)

SPECIAL STATEMENT:

THE CERTIFICATION IS VALID ONLY IN CONNECTION TO THE TEST REPORT NUMBER W6M22011-20420-E-11 AND TO THE SAMPLE HAS BEEN TESTED BY WORLDWIDE TESTING SERVICES (TAIWAN) CO., LTD.

December 29, 2020

(Date)

Rex Kao

Rex Kao, Laboratory Director