



EC Declaration of Conformity

We:

KINISIFORO Ltd.Lamprou Charalampous 8,

Akrounta Limassol 4552

CYPRUS

Tel: +357 99 353 959 Web: www.kinisiforo.com

Email: onisiforos@kinfsiforoltd.com

Declare under our sole responsibility that the product,

KINISIFORO HOSPITAL UNIT

with serial no

2022-KHU-XXX

with Basis UDI-DI

XXX-KHU

to which this documentation relates, is in conformity with the following documents:

European Regulation (EU) 2017/745 for Medical device

Safety of Machinery EN 292-2

Directive: Machinery Directive 2006/42/EC

Low Voltage Directive 2014/35/EU,

Electromagnetic Compatibility Directive 2014/30/EU

Risk Classification:

CLASS 1. (Active Medical Device as per Annex IX, section III, Classification Rule 12.)

The technical file is kept and maintained by the manufacturer.

Date of Issue: 31th of August 2022

Place of Issue: Limassol-Cyprus

Onisiforos Hadjionisiforou

CEO of KINISIFORO LTD

Signed (or sealed) this day in my presence by ONICIPOLO NOTICIPOLO

As the Certifying Officer, I certify only the signature which appears on the Liment and assume no responsibility for the content this document, intertheony whereof I have hereto set my hand and official seat.

this day of Alust

Fees: €5,00

CHRISTOFORDS DIANELLOS. Ceptifying Officer





CHR. DIANELLOS

This is to certify that the signature _____CHR_DIANELLOS

0 6 SEP-2022

District

Antros Vasileiadi

APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. Country: Cyprus

This public document

- 2. has been signed by Antros Vasileiadis
- 3. acting in the capacity for District Officer
- 4. bears the seal/stamp of District Administration of Limassol, Ministry of Interior

Certified

5. at APOSTILLE - LIMASSOL MJPO OFFICE

6. the 07/09/2022

- 7. by Despo Xenofontos
- 8. No LIM MJPO-LIM 000270045/2022
- 9. Seal/stamp:

10. Signature:



For Permanent Secretary Ministry of Justice and Public Order 84542189

signed (or scaled) this day to my presence by

As the Certifying On Lar, a certify only the signifiare which appears notify. Liment and assume no responsibility for the content. In a decreece, in territo any whereast across becase some property sear.

Chiestorones Blancilles Certifold Officer

Fees (5.00





Medical and Public Health Services Cyprus Medical Devices Competent Authority

File No.: I.Y 5.23.005.13.16

Tel No.: 22 605574 Fax No: 22 468427

2 September 2022

Kinisiforo Ltd

(Attn: Mr Hadjionisiforou Onisiforos)

Certificate of Free Sale for Exportation of Medical Devices

This is to notify that **Kinisiforo Ltd** is a medical devices manufacturer located in Cyprus with contact details:

Product name:	Kinisiforo Hospital Unit
Product Classification:	Class I (Rule 12)
Manufacturer Name:	Kinisiforo Ltd
Address:	Lamprou Charalambous 8 Arkounda, 4552 Limassol ,Cyprus
Telephone:	+357 99 353 959
Email:	onisiforos@kinisiforoltd.com
Web Site:	www.kinisiforo.com
Contact Person:	Mr Hadjionisiforou Onisiforos

The product detailed in the above schedule has been checked, registered and CE marked according to European regulation (EU) 2017/745 concerning Medical Devices and therefore may be freely sold in all member states of the European Economic Area including Cyprus.

Valid until 15/9/2023.

for Cyprus Medical Devices
Competent Authority



REPUBLIC OF CYPRUS

He No.: 1.Y 5.23.005,13:16 el No.: 22 605574

artificate of Free Sale for Exportation of Medical Devices

APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. Country: Cyprus

This public document

- 2. has been signed by Christiana Valianti
- 3. acting in the capacity for Director
- 4. bears the seal/stamp of Medical & Public Health Services, Ministry of Health

Certified

- 5. at APOSTILLE LIMASSOL MJPO OFFICE
- 7. by Despo Xenofontos
- 8. No LIM MJPO-LIM 000270046/2022
- 9. Seal/stamp:



10. Signature:

For Permanent Secretary Ministry of Justice and Public Order 38243461

6. the 07/09/2022





Medical and Public Health Services Cyprus Medical Devices Competent Authority

File No: 5.23.005.13.16

Tel No: 22605574

Fax No: 22605491

E-Mail: cymda@mphs.moh.gov.cy

2 September 2022

Kinisiforo Ltd

Lamprou Charalambous 8 Arkounta Limassol 4552 Cyprus

Tel: +357 99 353 959

Email: onisiforos@kinisiforoltd.com

Subject: Registration of persons responsible for placing on the Market Medical Devices according to Regulation (EU) 2017/745

I am instructed on behalf of the Cyprus Medical Devices Authority to inform you that Manufacturer Name:- Kinisiforo Ltd, located at Manufacturer Address:-Charalambous 8, Arkounta Limassol 4552, Cyprus has been added to the Medical Devices Manufacturers Registry as the manufacturer of the product Product Name:- Kinisiforo Hospital Unit, classification of the product:- Class I

Your registration is based upon your declaration on your application form dated 19/08/2022 and means that you should now be operating under the Medical Devices Regulation (EU) 2017/745 for the products you asked us to register, by fully complying with the essential requirements, CE marking this product or labelling it as such.

Please inform us of any changes to the company information, or to the technical file of the product before its implementation. Additional editions of products or modifications of the product that are not included in the technical file are not considered as approved by the Competent Authority to be placed on the market.





Medical and Public Health Sarvices

Connectent Authorit

File No. 5.23.005.13.10

rel No: 12605574

Fax No. 22603491

E-Mail: cymda@mphs.moh.gov.cy

E September 2022

Kinisiforo i.td Lamprou Charalambous 8 Arkounta Limassol 4552 Cyprus Tel: 4357 99 353 959

Subject: Registration of persons responsible for placing on the Market
Medical Devices according to Regulation (EU) 2017/745

an instructed on behalf of the Cyprus Medical Devices Authority to inform you that Manuforturer Names. Kinisifora Ltd., located at Manuforturer Address. Lampson Charalambous & Autounta Limassal 4552, Cyprus has been added to the Medical Devices Macufacturers Registry as the manufacturer of the product. Product Nome. Kinisifora Haspital Linit. electification of the product. Class I

Your capturation is based upon your declaration on your application form dated 19/08/2022 and means that you should now be operating upder the intentional Devices Regulation (EU) 2017/745 for the products you asked us to register, by fully complying with the essential regulations of the products of the product of shall be a complete to the product of the product of shall be a complete to the product of the p

Places inform us of any changes to the company information, or to the technical file of the product before its implementation. Additional editions of product that are not included in the technical file are viot considered as approved by the Competent Authority to be pieced on the market.

If you stop placing devices on the market you should inform us so that we can amend our records.

It is noted that the Competent Authority may change its decision in the event that new information is brought to its attention.

The Medical Devices Competent Authority of Cyprus is at your disposal for any further clarifications.

Valid until 15/9/2023.

(C. Valianti)

for Cyprus Medical Devices Competent Authority It is noted that the Competent Authority may change its decision in the event that neverteer that the event that never the event that the event that the

The Medical Devices Competent Authority of Cyprus is at your disposal for any furtherlarifications

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1. Country: Cyprus

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Certified

5. at APOSTILLE - LIMASSOL MJPO OFFICE

6. the 07/09/2022

- 7. by Despo Xenofontos
- 8. No LIM MJPO-LIM 000270048/2022

9. Seal/stamp:

10. Signature:

For Permanent Secretary
Ministry of Justice and Public Order
32123772





QUALITY MANAGEMENT SYSTEM

CERTIFICATE

This is to certify that the quality management system of

KINISIFORO LTD

LAMPROU CHARALAMPOU 8, AKROUNDA, 4522 LIMASSOL CYPRUS

has been assessed by HTCert and found to comply with

EN ISO 13485:2016

Scope of certificate:

Certificate No: Original Approval: 16/09/2020

1210C02200901

References:

WO01 1210 01

Issue Date: Valid until:

16/09/2020 15/09/2023



Design, development, production, installation and technical support of "Kinisiforo" medical devices

For and on behalf of HTCert

GEORGE PAPPOUS Managing Director

FILIPPOS KOTTIS Certification Director











a Certifying Officer of Limassol, appointed by the Minister of the interior of the Rebublic of Cyprus, under the Certifying Officers Law, 165(I)2012, to certify signatures and seals and that the seal opposite the said signature is that of the Certifying Officer of Limassol. The District Officer certifies only the signature and the seal of the Certifying Officer and assumes no responsibility for the content of this document LIMASSCL - CYPRUS

0-6-SEP-2022

Vasileiad

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6. the 07/09/2022

- 7. by Despo Xenofontos
- 8. No LIM MJPO-LIM 000270045/2022
- 9. Seal/stamp:

10. Signature:



For Permanent Secretary Ministry of Justice and Public Order

84542189

the subject of the and in my procedure as CHIUSTOFOLKS DIAUELLO CHIUSTOFOLKS DIAUELLO Lettering Officer