ΕΘΝΙΚΟ ΚΕΝΤΡΟ ΑΞΙΟΛΟΓΗΣΗΣ
ΤΗΣ ΠΟΙΟΤΗΤΑΣ & ΤΕΧΝΟΛΟΓΙΑΣ
ΣΤΗΝ ΥΓΕΙΑ Α.Ε.
NATIONAL EVALUATION CENTER
OF QUALITY & TECHNOLOGY
IN HEALTH S.A.

ΠΙΣΤΟΠΟΙΗΤΙΚΟ ΕΚ / EC CERTIFICATE

ΔΙΑΣΦΑΛΙΣΗ ΠΟΙΟΤΗΤΑΣ ΠΑΡΑΓΩΓΗΣ/ PRODUCTION QUALITY ASSURANCE

Πιστοποιείται ότι ο παρακάτω αναφερόμενος κατασκευαστής έχει καθιερώσει και εφαρμόζει σύστημα διασφάλισης της ποιότητας σύμφωνα με τις απαιτήσεις της Οδηγίας 93/42/ΕΟΚ, Παράρτημα V και της ενσωμάτωσης της στην ελληνική νομοθεσία,
για την κατασκευή και τον τελικό έλεγχο των προϊόντων που αναφέρονται στο παρόν πιστοποιητικό.
Το πιστοποιητικό υπόκειται στους όρους και τις προϋποθέσεις που αναγράφονται στην επόμενη σελίδα.
Οποιεσδήποτε σημαντικές αλλαγές στο σχεδιασμό ή την κατασκευή μπορεί να καταστήσουν το πιστοποιητικό άκυρο.

We hereby certify that the under mentioned manufacturer has established and maintains a quality assurance system according to the requirements of Directive 93/42/EEC, Annex V and its transposition in Greek legislation,
for the manufacture and final inspection of the products mentioned in this certificate.
The certificate is subject to terms and conditions overleaf.
Any significant changes in design or manufacture may render this certificate invalid.

Αριθμός Πιστοποιητικού / Certificate Number: 302081031M

Το παρόν εκδίδεται προς αντικατάσταση του υπ' αριθ. 302081031AD πιστοποιητικού λόγω απομάκρυνσης προϊόντων.
The present is issued to replace certificate nr 302081031AD due to products removal.

Κατασκευαστής:	**ΚΑΡΑΜΠΙΝΗΣ MEDICAL Α.Ε.**
Manufacturer:	**KARABINIS MEDICAL S.A.**
Εγκατάσταση:	**Λ. ΛΑΥΡΙΟΥ 151, 190 02 ΠΑΙΑΝΙΑ ΑΤΤΙΚΗ.**
Facility:	**151, LAVRIOU AVEN., 190 02 PAIANIA, ATTIKI GREECE.**
Προϊόντα:	**ΩΣ ΕΧΟΥΝ ΣΕ ΠΑΡΑΡΤΗΜΑ.**
Products:	**AS LISTED IN ANNEX.**
Κατηγοριοποίηση Προϊόντων:	**ΩΣ ΕΧΟΥΝ ΣΕ ΠΑΡΑΡΤΗΜΑ.**
Devices Classification:	**AS LISTED IN ANNEX.**
Ημερομηνία αρχικής έκδοσης:	**09/07/1998**
First issue date:	
Ημερομηνία τρέχουσας έκδοσης:	**17/06/2021**
Current issue date:	
Ισχύει μέχρι:	**24/07/2023**
Valid until:	
Έκθεση επιθεώρησης:	**200071031**
Audit report:	

ΠΙΚΡΟΥ - ΜΩΡΑΪΤΑΚΗ ΕΛΕΥΘΕΡΙΑ, Πρόεδρος & Διευθύνουσα Σύμβουλος
PIKROU - MORAITAKI ELEFTHERIA, President & Managing Director

ΣΜΥΡΝΗΣ 13-15 | 165 62 ΓΛΥΦΑΔΑ • 13-15 SMYRNIS | 165 62 GLYFADA - GREECE
T: +30 2132026200 | F: +30 210 9615464 | e-mail: info@ekapty.gr | www.ekapty.gr

ΠΑΡΑΡΤΗΜΑ ΤΟΥ ΥΠ. ΑΡΙΘΜ. 302081031Μ ΠΙΣΤΟΠΟΙΗΤΙΚΟΥ

ANNEX No. 302081031M CERTIFICATE.

- **Κατηγορία / Classification IIa**

ΙΑΤΡΟΤΕΧΝΟΛΟΓΙΚΟ ΠΡΟΪΟΝ / MEDICAL DEVICE	ΤΥΠΟΣ / BRAND NAME
1. ΑΠΟΣΤΕΙΡΩΜΕΝΑ ΟΦΘΑΛΜΙΚΑ ΕΠΙΘΕΜΑΤΑ / STERILE EYE PADS	ALFA GAUZE VAMMAT, ALFASHIELD.
2. ΑΠΟΣΤΕΙΡΩΜΕΝΗ ΓΑΖΑ ΜΕ ΑΤΜΟ/ STERILE GAUZE WITH STEAM	ALFASHIELD

- **Κατηγορία / Classification IIb**

ΙΑΤΡΟΤΕΧΝΟΛΟΓΙΚΟ ΠΡΟΪΟΝ / MEDICAL DEVICE	ΤΥΠΟΣ / BRAND NAME
3. ΝΕΦΕΛΟΠΟΙΗΤΕΣ / NEBULIZERS	ALFACHEK NEB TRAVEL

ΠΙΚΡΟΥ - ΜΩΡΑΪΤΑΚΗ ΕΛΕΥΘΕΡΙΑ, Πρόεδρος & Διευθύνουσα Σύμβουλος
PIKROU - MORAITAKI ELEFTHERIA, President & Managing Director

ΕΘΝΙΚΟ ΚΕΝΤΡΟ ΑΞΙΟΛΟΓΗΣΗΣ
ΤΗΣ ΠΟΙΟΤΗΤΑΣ & ΤΕΧΝΟΛΟΓΙΑΣ
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ΟΡΟΙ & ΠΡΟΫΠΟΘΕΣΕΙΣ / TERMS & CONDITIONS

1. Για αποστειρωμένα προϊόντα κατηγορίας Ι, η πιστοποίηση αφορά μόνο τα θέματα επίτευξης και διατήρησης της αποστείρωσης.
For class I sterile products, the certificate covers only the aspects of manufacture concerned with securing and maintaining sterile conditions.

2. Για προϊόντα κατηγορίας Ι με λειτουργία μέτρησης, η πιστοποίηση αφορά μόνο τα θέματα συμμόρφωσης των προϊόντων προς τις μετρολογικές απαιτήσεις.
For Class I devices with a measuring function the certificate covers only the aspects of manufacture concerned with the conformity of the products with metrological requirements.

3. Για προϊόντα κατηγορίας ΙΙΙ, είναι απαραίτητο ένα συμπληρωματικό πιστοποιητικό Εξέτασης Τύπου σύμφωνα με τις απαιτήσεις της Οδηγίας 93/42/ΕΟΚ, Παράρτημα ΙΙΙ.
For class III products an additional Type Examination certificate is required according to the requirements of 93/42/EEC, Annex III.

4. Το πιστοποιητικό ισχύει μόνα για τα προϊόντα και τις εγκαταστάσεις που αναφέρονται.
The certificate is valid only for the products and the facilities mentioned.

5. Θα πραγματοποιούνται περιοδικές επιθεωρήσεις επιτήρησης όπως αναφέρεται στην Οδηγία 93/42/ΕΟΚ, με σκοπό να επαληθεύεται ότι ο κατασκευαστής διατηρεί και εφαρμόζει το σύστημα ποιότητας.
Periodical surveillance as referred in 93/42/EEC will be held in order to verify that the manufacturer maintains and applies the quality system.

6. Όταν τηρούνται τα ανωτέρω, ο κατασκευαστής μπορεί να συντάσσει δήλωση συμμόρφωσης ΕΚ και να επιθέτει τη σήμανση CE 0653 στα καλυπτόμενα προϊόντα.
When meeting with the terms and conditions above, the manufacturer may draw up an EC declaration of conformity and legally affix the CE 0653 mark.

ΠΙΚΡΟΥ - ΜΩΡΑΪΤΑΚΗ ΕΛΕΥΘΕΡΙΑ, Πρόεδρος & Διευθύνουσα Σύμβουλος
PIKROU - MORAITAKI ELEFTHERIA, President & Managing Director

Το Εθνικό Κέντρο Αξιολόγησης της Ποιότητας και Τεχνολογίας στην Υγεία (ΕΚΑΠΤΥ) είναι Κοινοποιημένος Οργανισμός σύμφωνα με την Οδηγία 93/42/ΕΟΚ περί των ιατροτεχνολογικών προϊόντων, με αριθμό αναγνώρισης 0653.
National Evaluation Center of Quality & Technology in Health S.A. (EKAPTY) is a Notified body according to Council Directive 93/42/EEC concerning medical devices, with identification number 0653.

ΣΜΥΡΝΗΣ 13-15 | 165 62 ΓΛΥΦΑΔΑ • 13-15 SMYRNIS | 165 62 GLYFADA - GREECE
T: +30 2142026200 | F: +30 210 9615464 | e-mail: info@ekapty.gr | www.ekapty.gr

TÜV NORD CERT GmbH, Am TÜV 1, 45307 Essen, Germany

Karabinis Medical S.A.
151, Lavriou Ave
19002 Peania
Attiki, Greece

TÜV NORD CERT GmbH
Am TÜV 1
45307 Essen
Germany

Phone: +49 201 825 2236

medical@tuev-nord.de
tuev-nord-cert.com/en

TÜV®

Reference	Contact	Direct Dial	Date
25.9328/800008/KO	E-Mail: keconomidi@tuv-nord.com	Tel.: +30 2314443610	7 March 2025

Notified Body Confirmation Letter
Reference: P11F014e / 18.07.2024

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, TUV NORD CERT GmbH, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0044 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Karabinis Medical S.A.

151, Lavriou Ave

19002 Peania

Attiki, Greece

SRN Number: **GR-MF-000023526**

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written

agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 March 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body,

i. V. Caro Schmidt
Head of Project Management
Medical Devices International
TÜV NORD CERT GmbH
Notified Body for Medical Devices

i. A. Dr. Benjamin Hoy
Head of TIC Management
Medical Devices International
TÜV NORD CERT GmbH
Notified Body for Medical Devices

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable.

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Device 1 Sterile Non-Woven Swabs (Sterile Non-woven Gauze swabs)	Class I devices placed on the market in sterile condition	N/A	Certificate No. 1999C05210501, HTCert 2803 (last issued 23.05.2021, valid until 26.05.2024)
Device 2 Sterile Non-Woven Adhesive Pads (Sterile adhesive dressings)	Class I devices placed on the market in sterile condition	N/A	Certificate No. 1999C05210501, HTCert 2803 (last issued 23.05.2021, valid until 26.05.2024)
Device 3 Water-Resistant Adhesive Pads (Sterile adhesive dressings)	Class I devices placed on the market in sterile condition	N/A	Certificate No. 1999C05210501, HTCert 2803 (last issued 23.05.2021, valid until 26.05.2024)
Device 4 Medical Gauze Sterile (EO) (Sterile and non-sterile gauze)	Class IIa	N/A	Certificate No. 1999C05210501, HTCert 2803 (last issued 23.05.2021, valid until 26.05.2024)
Device 5 Medical Gauze Non-Sterile (Sterile and non-sterile gauze)	Class IIa	N/A	Certificate No. 1999C05210501, HTCert 2803 (last issued 23.05.2021, valid until 26.05.2024)
Device 6 Gauze Balls Non-Sterile (Sterile and non-sterile gauze)	Class IIa	N/A	Certificate No. 1999C05210501, HTCert 2803 (last issued 23.05.2021, valid until 26.05.2024)
Device 7 Gauze balls X-ray detectable Non-Sterile (Sterile and non-sterile gauze)	Class IIa	N/A	Certificate No. 1999C05210501, HTCert 2803 (last issued 23.05.2021, valid until 26.05.2024)
Device 8 Laparotomy Gauze Non-Sterile (Sterile and non-sterile gauze)	Class IIa	N/A	Certificate No. 1999C05210501, HTCert 2803 (last issued 23.05.2021, valid until 26.05.2024)
Device 9 Aneroid Blood Pressure Monitor (Aneroid sphygmomanometers)	Class I devices with a measuring function	N/A	Certificate No. 1999C05210501, HTCert 2803 (last issued 23.05.2021, valid until 26.05.2024)
Device 10 Digital Thermometer (Digital thermometers)	Class IIa	N/A	Certificate No. 1999C05210501, HTCert 2803

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
			(last issued 23.05.2021, valid until 26.05.2024)
Device 11 Flexy Digital Thermometer (Digital thermometers)	Class IIa	N/A	Certificate No. 1999C05210501, HTCert 2803 (last issued 23.05.2021, valid until 26.05.2024)
Device 12 Medical Gauze Sterile (Steam)	Class IIa	N/A	Certificate No. 302081031M, EKAPTY 0653 (last issued 17.06.2021, valid until 24.07.2023)
Device 13: Sterile Eye Pads	Class IIa	N/A	Certificate No. 302081031M, EKAPTY 0653 (last issued 17.06.2021, valid until 24.07.2023)

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Device 1 Syringes with Needles	Class IIa	New device	N/A
Device 2 Syringes without Needles	Class IIa	New device	N/A
Device 3 Needles	Class IIa	New device	N/A

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2025.03.07	25.9328/800008	Initial issuance following successful transfers of certificates from NoBo EKAPTY 0653 & HTCert 2803