HTCert

Health Technology Certification

EC-CERTIFICATE

PRODUCTION QUALITY ASSURANCE

This is to certify that the
quality management system of

KARABINIS MEDICAL S.A.

151, Lavriou Avenue, Peania, Attiki 19002, Greece

for manufacturing and final testing of

Certificate No: 1999C05210501
Issue Date: 23/05/2021
Original Approval: 23/05/2021
Valid until: 26/05/2024
References: W001 1999 01

HTCert is a Notified Body according to Council Directive 93/42/EEC concerning medical devices with identification number **2803**

Details are given overleaf

fulfills the requirements of Annex V of Council Directive 93/42/EEC.

The use of CE Marking followed by the HTCert Notified Body identification number 2803 for the devices listed on the certificate is hereby authorised. The certificate remains valid subject to satisfactory surveillance audits, periodic or unexpected. Any significant changes in design or manufacture may render this certificate invalid. For class I sterile devices the certificate covers only the aspects of manufacture concerned with securing and maintaining sterile conditions. 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.

For and on behalf of HTCert

GEORGE PAPPOUS
Managing Director

FILIPPOS KOTTIS
Certification Director

G.E.I. HEALTH TECHNOLOGY CERTIFICATION LIMITED
81-83
GRIVAS DIGHENIS AV.
CY-1090 NIKOSIA
CYPRUS
T.I.C.: 10360886V

JACOVIDES TOWER, 81-83 GRIVAS DIGHENIS AV. CY-1090, NICOSIA, CYPRUS, T: +357 220 60 771, F: +357 220 60 772
info@htcert.com, www.htcert.com

HTCert

Health Technology Certification

Attachment to Certificate

No: 1999C05210501 Issued: 23/05/2021

Class I sterile devices:

- Sterile Non-Woven Gauze swabs
- Sterile adhesive dressings

Class I devices with measuring function:

- Aneroid sphygmomanometers

Class IIa devices:

- Sterile and non-sterile gauze
- Digital thermometers
- Blood pressure monitors

For and on behalf of HTCert

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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