CERTIFICATO CE

Certificato n. 2104/MDD

Dichiarazione di approvazione del sistema qualità

(Sistema completo di garanzia qualità)

Visto l'esito delle verifiche condotte in conformità all'Allegato II, con l'esclusione del punto 4, della direttiva 93/42/CEE e s.m.i., si dichiara che la ditta:

CAMARK S.A.

61400 Axioupoli - Industrial Park Axioupoli (GRC) - Greece

mantiene nello stabilimento di:

61400 Axioupoli - Industrial Park Axioupoli (GRC) - Greece

un sistema qualità che assicura la conformità dei seguenti prodotti:

Suture chirurgiche non riassorbibili

Modd. come da documento "Allegato al Certificato CE no. 2104/MDD - Elenco dei Dispositivi" rev. 0 del 2021/01/27; tale allegato costituisce parte integrante e sostanziale del presente certificato.

ai requisiti essenziali della direttiva suddetta ad essi applicabili (in tutte le fasi dalla progettazione al controllo finale) ed è sottoposta alla sorveglianza prevista dal punto 5 dell'Allegato II. Per i dispositivi in classe III questo certificato è valido solamente con il relativo certificato di esame CE della progettazione di Allegato II.4.

Riferimento pratiche IMQ:
DM20-0055064-01.

Questa Dichiarazione di approvazione è rilasciata dall'IMQ S.p.A. quale organismo notificato per la direttiva 93/42/CEE e s.m.i. Il numero identificativo dell'IMQ S.p.A. quale organismo notificato è: 0051.

Emesso il: 2021-01-27

Giorgi Fulvio
IMQ

DocuSign

Data scadenza: 2024-05-26

EC CERTIFICATE

Certificate No 2104/MDD

Full Quality Assurance System Approval Certificate

On the basis of our examination carried out according to Annex II, excluding section 4, of the Directive 93/42/EEC and its revised version, we hereby certify that:

CAMARK S.A.

61400 Axioupoli - Industrial Park Axioupoli (GRC) - Greece

manages in the factory of:

61400 Axioupoli - Industrial Park Axioupoli (GRC) - Greece

a quality assurance system ensuring the conformity of the following products:

Non absorbable surgical sutures

Type ref. as to document "Annex of EC Certificate no. 2104/MDD - Device List" rev. 0 dated 2021/01/27; this annex is integral and substantial part of this certificate.

with the relevant essential requirements of the aforementioned directive (from design to final inspection and testing) and it is subject to surveillance as specified in section 5 of Annex II. For class III devices, this certificate is valid only with the relevant EC Design-Examination Certificate of Annex II.4.

Reference to IMQ files Nos:
DM20-0055064-01.

This Approval Certificate is issued by IMQ S.p.A. as Notified Body for the Directive 93/42/EEC and its revised version. Notified Body notified to European Commission under number: 0051.

Date: 2021-01-27

Giorgi Fulvio
IMQ

DocuSign

Expiry Date: 2024-05-26

Allegato al Certificato CE n. 2104/MDD - Elenco dei Dispositivi

Annex of EC Certificate no. 2104/MDD - Device List

rev. 0 del/of **2021/01/27**

Categoria di dispositivo: Device category:	**Suture chirurgiche non riassorbibili** Non absorbable surgical sutures
Modello/i: Model(s):	**32.YXXXX.00** **dove** / where: **3 = identifica la famiglia di prodotti "Suture chirurgiche non riassorbibili" (valore fisso)** identifies the family of products "Non-resorbable surgical sutures" (fixed value) **2 = identifica che il prodotto è sterile (valore fisso)** identifies that the product is in steril condition (fixed value) **Y = identifica la tipologia di distribuzione dei prodotti e può assumere i seguenti valori:** identifies the type of distribution of the products and can assume the following values: **Z = codice a catalogo o standard per progetti in "Distributed by" (valore fisso)** catalog or standard code for projects in "Distributed by" (fixed value) **N = Mercato UE (esclusa l'Italia) (valore fisso)** EU market (Italy excluded) (fixed value) **I = Mercato italiano (valore fisso)** Italian market (fixed value) **X = Mercato extra UE (valore fisso)** Non-EU market (fixed value) **XXXX = carattere numerico progressivo che identifica la combinazione ago – filo – materiale del filo e può assumente i seguenti valori: da 0001 a 9999** progressive number that identifies the combination needle – thread – thread material and can assume the following values: from 0001 to 9999 **I materiali del filo approvati sono i seguenti:** The approved thread materials are the followings: • **PTFE** • **poliammide** / *polyamide* • **polipropilene** / *polypropylene* • **poliestere** / *polyester* • **seta** / *silk* **.00 = identifica il prodotto finito (valore fisso)** identifies finished product (fixed value)
Marca/Marche: Trade mark(s):	**CAMARK**

Manufacturer's Declaration

in relation to 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, in particular with respect to

- the validity of certificates issued under Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and*
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	*CAMARK S.A.*
Manufacturer address and contact details	*Industrial Park Axioupoli – 61400 Greece* *info@camark.gr*
Single Registration Number (SRN) (if available)	*Not yet available* *EUDAMED Application ID: APP000045257*

Authorised Representative name	Not Applicable
Authorised Representative address and contact details	Not Applicable
Single Registration Number (SRN)	Not Applicable

Notified body name	*IMQ*
Notified body number	*0051*
Directive Certificate number to which this confirmation is made	*2104/MDD*
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	*26 May 2024*
End date of extended validity/transition period	*31 December 2028*

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and*
- the listed **devices** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

- **Directive Certificate** as listed above or in the attached schedule
  - Directive Certificate covering the listed devices was issued after 25 May 2017, was valid on 26 May 2021 and have not been withdrawn afterwards.
  - Expired/expires after 20 March 2023:

    Formal application to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has been submitted by us to a notified body for the devices listed in the attached schedule and a signed written agreement is in place in accordance with Section 4.3, second subparagraph of Annex VII MDR.

- **Quality Management System (QMS)**
  - A QMS in accordance with Article 10(9) MDR is in place.
  - A notified body has issued the certificate for the MDR-compliant QMS (*ref. ISO 13485 Certificate n. 0149.2024 current issue dated 12/02/2024 – IMQ 0051).*

- **Devices as listed in the attached schedule**
  - The devices continue to comply with the MDD.
  - There are no significant changes in the design and intended purpose.
  - The devices do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

CAMARK S.A.

April 24th, 2024

Alberto Colombo – EMEA RA Manager
Email: alberto.colombo@omniaspa.eu
Office: +39 0524.527453
Cell: +39 335 826 0560

CAMARK
EFFICIENT SURGICAL SOLUTIONS

Schedule of Devices

The above Manufacturer's Declaration is valid for the following class IIb medical devices according to rule 8 of Directive 93/42/EEC, Annex IX belonging to the **Non Absorbable Surgical Sutures** product family. Device list:

Identification of the device	Device Description	Directive Certificate number to which this confirmation is made	Original expiry date as indicated on the Directive Certificate prior to the extension of the validity	Notified Body name and number that issued the Directive Certificate	End date of extended validity / transition period
*32.YXXXX.00**	*Non absorbable surgical sutures*	*2104/MDD*	*26 May 2024*	*IMQ - n. 0051*	*31 December 2028*

*where:

- 3 = identifies the family of products "Non-resorbable surgical sutures" (fixed value)
- 2 = identifies that the product is in steril condition (fixed value)
- Y = identifies the type of distribution of the products and can assume the following values:
  - Z = catalog or standard code for projects in "Distributed by" (fixed value)
  - N = EU market (Italy excluded) (fixed value)
  - I = Italian market (fixed value)
  - X = Non-EU market (fixed value)
- XXXX = progressive number that identifies the combination needle – thread – thread material and can assume the following values: from 0001 to 9999

The approved thread materials are the followings:

- PTFE
- polyamide
- polypropylene
- polyester
- silk

- 00 = identifies finished product (fixed value)