

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	<i>CAMARK S.A.</i>
Manufacturer address and contact details	<i>Industrial Park Axioupoli 61400 Axioupoli Greece</i>
Single Registration Number (SRN) (if available)	<i>In the process of assignment</i>

Authorised Representative name (if applicable)	<i>Not Applicable</i>
Authorised Representative address and contact details	<i>Not Applicable</i>
Single Registration Number (SRN) (if available)	<i>Not Applicable</i>

Notified body name (if applicable)	<i>HT Cert</i>
Notified body number (if applicable)	<i>2803</i>
Directive Certificate number(s) to which this confirmation is made (if applicable)	<i>1145C03191101 1145C04191101</i>
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	<i>27th of May 2024</i>
End date of extended validity/transition period	<i>31st of December 2027</i>

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,

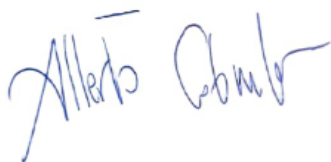
namely by fulfilling the following conditions:

- **Directive Certificate** as listed above
 - 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Certificate covering the listed devices was issued after 25 May 2017, was valid on 26 May 2021 and have not been withdrawn afterwards.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 after 20 March 2023:
A formal application has been submitted to the notified body, as per Section 4.3, first subparagraph of Annex VII MDR, for conformity assessment of the devices listed in the attached schedule. Additionally, a signed written agreement has been established in accordance with Section 4.3, second subparagraph of Annex VII MDR prior to September 26, 2024.
- **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*).
- **Device(s) 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.

18th of April 2024



Alberto Colombo – EMEA RA Manager

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Office: +39 0524.527453

Cell: +39 335 826 0560

Schedule of Devices

The above Manufacturer's Declaration is valid for the following class III medical devices according to rules 8 of Directive 93/42/EEC, Annex IX belonging to the **ABSORBABLE SUTURES** product family covering *PGA, PGLA, PGLA RAPID, PGCL, PDO*.

Identification of the device	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	Notified Body name and number where the MDR application was lodged	End date of extended validity / transition period
32.Z6500.00	1145C03191101 1145C04191101	27/05/2024	HT Cert - NB n° 2803	HT Cert - NB n° 2803	31/12/2027
32.Z6501.00	1145C03191101 1145C04191101	27/05/2024	HT Cert - NB n° 2803	HT Cert - NB n° 2803	31/12/2027
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32.Z6509.00	1145C03191101 1145C04191101	27/05/2024	HT Cert - NB n° 2803	HT Cert - NB n° 2803	31/12/2027
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32.Z3455.00	1145C03191101 1145C04191101	27/05/2024	HT Cert - NB n° 2803	HT Cert - NB n° 2803	31/12/2027



Health Technology Certification

EC-CERTIFICATE

DESIGN EXAMINATION

This is to certify that the manufacturer

CAMARK S.A.

**INDUSTRIAL PARK AXIOUPOLI
61400 AXIOUPOLI, GREECE**

for the design of

**Sterile Absorbable Surgical Sutures
with or without needles**

conforms to the provisions of the Council Directive 93/42/EEC.

The certificate is based on the result of the examination of the submitted design dossier according to Annex II, Section 4, of the Directive. Any changes which could affect conformity with the essential requirements of Directive 93/42/EEC, or with the conditions prescribed for use of the product must receive further approval from HTCert. For marketing of the products, a Full Quality Assurance System Certificate according to the requirements of Annex II, Section 3, of Council Directive 93/42/EEC is required.

For and on behalf of HTCert

GEORGE PAPPOUS
Managing Director

FILIPPOS KOTTIS
Certification Director

Certificate No: 1145C03191101

Issue Date: 28/11/2019

Original Approval: 28/11/2019

Valid until: 27/05/2024

Report No: W002 1145 01 - 05
W003 1145 01 - 05

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



Health Technology Certification

Attachment to Certificate

No: 1145C03191101

Issued: 28/11/2019

Product(s)	Description
PGA	PGA synthetic absorbable sterile surgical sutures braided Variable length from 45cm to 180cm - Thread diameter from 4 to 7/0 (USP classification)
PGLA	PGLA synthetic absorbable sterile surgical sutures braided Variable length from 45cm to 150cm - Thread diameter from 2 to 7/0 (USP classification)
PGLA RAPID	PGLA RAPID synthetic absorbable sterile surgical sutures braided Variable length from 45cm to 150cm - Thread diameter from 2 to 6/0 (USP classification)
PDO	PDO synthetic absorbable sterile surgical sutures monofilament Variable length from 45cm to 150cm - Thread diameter from 2 to 7/0 (USP classification)
PGCL	PGCL synthetic absorbable sterile surgical sutures monofilament Variable length from 45cm to 150cm - Thread diameter from 2 to 6/0 (USP classification)

For and on behalf of HTCert

GEORGE PAPPOUS
Managing Director

FILIPPOS KOTTIS
Certification Director