HTCert
Health Technology Certification

EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

HTCert Notified body (identification number 2803) certifies that

Th. Kazantzidis S.A. - MEDIPAC

Industrial Area,
611 00 Kilkis,
Greece

SRN: GR-MF-000027637

has drawn up the Technical Documentation in accordance with Regulation (EU) 2017/745, Annex II, for the device(s) presented on the following pages.
The assessment has been carried out according to Annex IX Chapter II of the Regulation and it was found that the technical documentation conforms to the relevant provisions.
The report referenced below summarizes the results of the assessment and includes information on all examinations and tests carried out, as well as reference to relevant CS and harmonized standards.
For the placing on the market of the devices covered by this certificate, an EU quality management system certificate according to Annex IX, chapters I and III is required.
Any changes which could affect conformity with the general safety and performance requirements of Regulation (EU) 2017/745, or with the conditions prescribed for use of the product must receive further approval from HTCert.
Further information may be requested from certification@htcert.com.

Certificate No: **C07 GR027637 2412 Rev.00**

Effective Date: 20/12/2024
Expiry Date: 19/12/2029
Assessment Report: FR_ GR027637_2412

For and on behalf of HTCert

GEORGE PAPPOUS
Managing Director

FILIPPOS KOTTIS
Certification Director

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Devices covered by the certificate

Classification:	III
Device Group:	H01020101 - MONOFILAMENT NON-ABSORBABLE SYNTHETIC SUTURES
Basic UDI-DI:	5206913PROFIMED8Q
Intended purpose:	Polytetrafluoroethylene surgical non-absorbable monofilament sutures are indicated for use in soft tissue ligation or approximation, excluding opthalmic surgery, microsurgery and peripheral neural tissue.
Device(s):	- PROFIMED - MONOSOFT - ELASYN

Conditions for / limitations to the validity of the certificate: N/A

Certificate history

Revision	Date	Description of changes
Rev. 00	20/12/2024	Initial issue

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EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX, Chapters I and III

HTCert Notified body (identification number 2803) certifies that

Th. Kazantzidis S.A. - MEDIPAC

Industrial Area,
611 00 Kilkis, Greece

SRN: GR-MF-000027637

has established, documented and implemented a quality management system in accordance with Regulation (EU) 2017/745. The conformity assessment has been carried out according to Annex IX Chapter I and III of the Regulation and it was found that the quality management system conforms to the relevant provisions.
The scope of certification, as well as further information and conditions, are described on the following page(s).
The quality management system is subject to periodical surveillance in accordance with Annex IX, Chapter 1, Section 3 of Regulation (EU) 2017/745.
The results of the assessment and information on all examinations and tests carried out are summarized in the report referred to below.
For the placing on the market of Class III devices or Class IIb implantable devices referred to in Article 52(4) subparagraph 2 covered by this certificate, an additional EU Technical Documentation Assessment certificate is required.
For Class I sterile devices, sterilized systems or procedure packs, the certificate covers only the aspects relating to establishing, securing, and maintaining sterile conditions. For Class I devices with a measuring function, the certificate covers only the aspects relating to the conformity of the devices with the metrological requirements. For Class I reusable surgical instruments, the certificate covers only the aspects relating to the reuse of the device, in particular cleaning, disinfection, sterilization, maintenance and functional testing and the related instructions for use.
Further information may be requested from certification@htcert.com.

Certificate No: **C08 GR027637 2412 Rev.00**

Effective Date: 20/12/2024
Expiry Date: 19/12/2029
Assessment Report: FR_ GR027637_2412

For and on behalf of HTCert

GEORGE PAPPOUS
Managing Director

FILIPPOS KOTTIS
Certification Director

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Devices covered by the certificate

Device :	Surgical non-absorbable monofilament Polytetrafluoroethylene suture
Classification:	III
Intended purpose:	Polytetrafluoroethylene surgical non-absorbable monofilament sutures are indicated for use in soft tissue ligation or approximation, excluding opthalmic surgery, microsurgery and peripheral neural tissue.

Conditions for / limitations to the validity of the certificate: N/A

Certificate history

Revision	Date	Description of changes
Rev. 00	20/12/2024	Initial issue