HTCert

Health Technology Certification

Digitally signed by Pereteatco Alina
Date: 2023.09.26 12:41:13 EEST
Reason: MoldSign Signature
Location: Moldova

EC-CERTIFICATE

FULL QUALITY ASSURANCE SYSTEM

This is to certify that the quality management system of

SIDAPHARM P.C

21, Stageiriti & 24, Em. Fili str Thessaloniki, 54352 Greece

Certificate No:	**1828C04210505**
Issue Date:	**20/05/2021**
Original Approval:	**20/05/2021**
Valid until:	**03/06/2023**
References:	**W001 1828 04**

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

for design and manufacture of

- OPHTHALMIC MICROSURGICAL KNIVES
- OPHTHALMIC MICROSURGICAL CANNULAS
- Trypan Blue Ophthalmic Solution
- Balanced Salt Solution BSS
- Ophthalmic Solution HPMC 2%

fulfills the requirements of Annex II exluding (4) 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 III devices covered by this certificate an EC Design Examination Certificate according to Annex II, Section 4 is required. 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

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