



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

for design and manufacture of

of devices as detailed overleaf

Certificate No:

1828C04210204

Issue Date:

23/02/2021

Original Approval: 07/04/2020

Valid until: References:

26/05/2024 W001 1828 01.

W001 1828 03

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

number 2803

fulfills the requirements of Annex II excluding (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 FILIPPOS KOTTIS Managing Director Certification Director GRIVAS DIGHENIS AV CY-1090 NIKOSIA

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Attachment to Certificate

No: 1828C04210204 Issued: 23/02/2021

Products Covered

- Sodium Hyaluronate Ophthalmic Solution, SIDA-VISC
- Hypromellose Ophthalmic Solution, SIDA-HPMC 2%
- Disposable Cartridge and Injector, SIDA-JECT
- Iris Retractor, SIDA-HOOKS
- PVA Eye Spears, SIDA-SPEARS
- Surgical Drapes
- Surgical Gowns
- Surgical Pack

Certificate History

Issue date	Certificate Number	Reason of issuance
07/04/2020	1828C04200401	First issue
07/09/2020	1828C04200902	Addition of products:
		 Hypromellose Ophthalmic Solution, SIDA-HPMC 2%
		 Disposable Cartridge and Injector, SIDA-JECT
		to the certification scope
21/10/2020	1828C04201003	Addition of Surgical Drapes, Gowns and Pack to the certification scope
23/02/2021	1828C04210204	Addition of products:
		o Iris Retractor, SIDA-HOOKS
		o PVA Eye Spears
		to the certification scope

For and on behalf of HTCert

GEORGE PAPPOUS

Managing Director

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GRIVAS DIGHENIS AV.

CY-1090 NIKOSIA
CYPRUS
T.I.C.: 10380886V

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