SIDAPHARM®
Ophthalmic & Medical Disposable Products

EC DECLARATION OF CONFORMITY

According to Annex II (exemption of section 4) of Council Directive 93/42/EEC concerning Medical Devices

Reference No.	: 1828C-01
Manufacturer	: SIDAPHARM P.C.
Facility Address	: 21, Stageiriti & 24, Em. Fili str., GR-543 52, Thessaloniki, Greece
Product	: **S_{IDA}-Visc Sodium Hyaluronate Ophthalmic Solution** *(Annex I)*
GMDN	: 35907
Classification	: **IIb**, according to Rule 8, Annex IX of Council Directive 93/42/EEC
Applicable Guidelines	: MEDDEV 2.4/1 Rev. 9 - June 2010 Rule 1

We hereby declare that the aforementioned products comply with all the essential requirements of Council Directive 93/42/EEC, concerning Medical Device, as amended by 2007/47/EC.

The compliance of this applicable quality assurance system has been certified by the "Health Technology Certification ", which is a Notified Body with identification number 2803.

The present is issued, according to EC Certificate No.: 1828C04200401, which is valid until 26/05/2024 and replaces any previous declaration might has been issued for this product.

For and on behalf of
SIDAPHARM P.C.

SIDAPHARM P.C.
21, Stageiriti & 24, Em. Fili str.
Thessaloniki GR-54352, Greece
T: +30 2310906660 - F: +30 2310989846
VAT Reg. No. EL[illegible]296038
Registration Number: 144520204000

Diana Mochintra
General Manager

Date: 07/04/2020

Digitally signed by Talpiş Andrei
Date: 2020.09.09 09:27:14 EEST
Reason: MoldSign Signature
Location: Moldova

ANNEX I

Description	Ref. No
Sodium Hyaluronate 1.0% (1,0 ml)	10000
Sodium Hyaluronate 1.4% (1,0 ml)	10005
Sodium Hyaluronate 1.6% (1,0 ml)	10006
Sodium Hyaluronate 1.8% (1,0 ml)	10002
Sodium Hyaluronate 2.0% (1,0 ml)	10009
Sodium Hyaluronate 3.0% (1,0 ml)	10007
Sodium Hyaluronate 1.0% (1,5 ml)	10010
Sodium Hyaluronate 1.4% (1,5 ml)	10014
Sodium Hyaluronate 1.6% (1,5 ml)	10016
Sodium Hyaluronate 1.8% (1,5 ml)	10018
Sodium Hyaluronate 3.0% (1,5 ml)	10030

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Medical Disposables

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Tel. +30 2310906660 Fax: +30 2310989846
info@sidapharm.gr

ANNEX II - LIST OF APPLICABLE STANDARDS

#	Standard Identification	Standard Name
1	EN ISO 13485	Medical devices - Quality management systems - Requirements for regulatory purposes
2	EN ISO 9001	Quality Management Systems-Requirements
3	EN 1041	Information supplied by the manufacturer of medical devices
4	EN 556-1	Sterilization of medical devices - Requirements for medical devices to be designated "Sterile" - Part 1: Requirements for terminally sterilized medical devices
5	EN ISO 10993-1	Biological evaluation of medical devices -Part 1: Evaluation and testing within a risk management process
6	EN ISO 10993-5	Biological evaluation of medical devices -Part 5: Tests for in vitro cytotoxicity
7	EN ISO 10993-10	Biological evaluation of medical devices -Part 10: Tests for irritation and delayed type hypersensitivity
8	EN ISO 10993-13	Biological evaluation of medical devices - Part 13: Identification and quantification of degradation products from polymeric medical devices
9	EN ISO 10993-18	Biological evaluation of medical devices -Part 18: Chemical characterization of materials
10	EN ISO 11138-3	Sterilization of health care products - Biological indicators -Part 3: Biological indicators for moist heat sterilization processes
11	ISO 11140-1	Sterilization of health care products - Chemical indicators -Part 1: General requirements
12	ISO 11140-4	Sterilization of health care products - Chemical indicators -Part 4: Class 2 indicators as an alternative to the Bowie and Dick-type test for detection of steam penetration
13	EN ISO 11607-1	Packaging for terminally sterilized medical devices -Part 1: Requirements for materials, sterile barrier systems and packaging systems
14	EN ISO 11607-2	Packaging for terminally sterilized medical devices -Part 2: Validation requirements for forming, sealing and assembly processes
15	EN ISO 11737-1	Sterilization of medical devices - Microbiological methods -Part 1: Determination of a population of microorganisms on products
16	EN ISO 11737-2	Sterilization Of Medical Devices - Microbiological Methods -Part 2: Tests Of Sterility Performed In The Definition, Validation And Maintenance Of A Sterilization Process
17	EN ISO 14644-1	Cleanrooms and associated controlled environments -Part 1: Classification of air cleanliness
18	EN ISO 14644-2	Cleanrooms and associated controlled environments -Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration
19	EN ISO 14644-3	Cleanrooms and associated controlled environments -Part 3: Test methods
20	EN ISO 14644-4	Cleanrooms and associated controlled environments -Part 4: Design, construction and start-up
21	EN ISO 14971	Medical devices - Application of risk management to medical devices
22	EN ISO 15223-1	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied -Part 1: General requirements
23	EN ISO 15798	Ophthalmic implants - Ophthalmic viscosurgical devices
24	EN ISO 17665-1	Sterilization of health care products - Moist heat -Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices
25	EN 62366-1	Medical devices -Part 1: Application of usability engineering to medical devices