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-02
Manufacturer	:	SIDAPHARM P.C.
Facility Address	:	21, Stageiriti & 24, Em. Fili str., GR-543 52, Thessaloniki, Greece
Product	:	**SIDA-HPMC 2%** Hypromellose Ophthalmic Solution 2% w/v (Ref. No:10011) GMDN: 35907
Classification	:	IIb, according to Rule 8, Annex IX of Council Directive 93/42/EEC
Guidelines Applicable	:	MEDDEV 2.4/1 Rev. 9 - June 2010 Rule 8

This Declaration of Conformity is issued under the sole responsibility of the manufacturer. SIDAPHARM hereby declares that the aforementioned product complies with all the essential requirements of Council Directive 93/42/EEC, concerning Medical Devices, 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, according to Council Directive 93/42/EEC, with identification number 2803.

The present is issued, according to EC Certificate No.: 1828C04210204, whose original expiry date was 26/05/2024, but it has been granted an extension, according to Regulation (EU) 2023/607, till 31/12/2028.

The present replaces any previous declaration has been issued for these products.

For and on behalf of:
SIDAPHARM P.C.

SIDAPHARM P.C.
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Diana Mochintra
General Manager

Date: 04/04/2024

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ANNEX I – Applied Standards

Standard Number	Title
EN ISO 13485:2016/AC: 2018	Medical devices - Quality management systems - Requirements for regulatory purposes
EN ISO 14971:2019	Medical devices - Application of risk management to medical devices
ISO 10005:2005	Quality management systems - Guide lines for quality plans
EN ISO 11607-1:2020	Packaging for terminally sterilized medical devices -Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-2:2020	Packaging for terminally sterilized medical devices -Part 2: Validation requirements for forming, sealing and assembly processes
EN ISO 10993-1:2020	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN 868-5:2009	Packaging for terminally sterilized medical devices - Part 5: Sealable pouches and reels of porous materials and plastic film construction - Requirements and test methods
EN 556-1:2001/AC:2006	Sterilization of medical devices – Requirements for medical devices to be designated "STERILE" - Part-1 Requirements for terminally sterilized medical devices
EN 556-2:2015	Sterilization of medical devices. Requirements for medical devices to be designated "STERILE". Requirements for aseptically processed medical devices
EN ISO 11737-1:2018	Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products
EN ISO 11737-2:2020	Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
EN 62366-1:2015+AC:2015+ AC:2016+A1:2020	Medical devices - Application of usability engineering to medical devices
EN ISO 10993-5:2009	Biological Evaluation of Medical Devices - Part 5, Tests for In vitro Cytotoxicity
EN ISO 10993-10:2010	Biological evaluation of medical devices – Part 10: Tests for irritation and delayed-type hypersensitivity
EN ISO 10993-12:2012	Biological evaluation of medical devices – Part 12: Sample preparation and reference materials
EN ISO 10993-17:2009	Biological evaluation of medical devices – Part 17: Establishment of allowable limits for leachable substances
EN ISO 10993-18:2009	Biological evaluation of medical devices – Part 18: Chemical characterization of materials
ISO 15223-1:2021	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
ISO 20417:2021	Information supplied by the manufacturer of medical devices
ISO 24971:2020	Medical devices — Guidance on the application of ISO 14971
EN ISO 15798:2013/ Amd 1: 2017	Ophthalmic implants – Ophthalmic viscosurgical devices
ISO 11138-2:2017	Sterilization of health care products - Biological indicators - Part 2: Biological indicators for ethylene oxide sterilization processes

ASTM F 1929 – 98 (2004)	Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
ISO 14644-1:2015	Cleanrooms and associated controlled environments — Part 1: Classification of air cleanliness by particle concentration
ISO 14644-2:2015	Cleanrooms and associated controlled environments — Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration
ISO 14644-3:2019	Clean rooms and associated controlled environments - Test methods
ISO 14644-4:2001	Clean rooms and associated control environments - Design, construction and start - up
ISO 14644-5:2004	Clean rooms and associated controlled environments - Operations
EN ISO 17665-1:2006	Sterilization of health care products- Moist heat - Requirements for the development validation & routine control of sterilization process for medical device
EN ISO 11138-3:2009	Sterilization of health care products biological
EN ISO 14155:2011/Cor 1:2011	Clinical investigation of medical devices for human subjects - Good clinical practice
ISO 2248:1985	Packaging - Complete, filled transport packages - Vertical impact test by dropping
ISO 14698-1:2003	Clean rooms and associated controlled environment - Biocontamination control - General principles and methods
ISO 14698 -2:2003	Cleanrooms and associated controlled environments - Biocontamination control -- Part 2: Evaluation and interpretation of biocontamination data
ISO 2859-1:1999	Sampling procedures for inspection by attributes - Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection
ISO 2859-2:1985	Sampling procedures for inspection by attributes - Part 2: Sampling plans indexed by limiting quality (l.Q) for isolated lot inspection
1P/EP/USP BP	Indian Pharmacopeia. European Pharmacopeia, United states of pharmacopoeia. British Pharmacopeia