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-12
Manufacturer	:	SIDAPHARM P.C.
Facility Address	:	21, Stageiriti & 24, Em. Fili str., GR-543 52, Thessaloniki, Greece
Product	:	**SIDA-BLUE & SIDA-BLUE PFS** Trypan Blue Ophthalmic Solution 0.06% w/v 1ml Vial Ref. No: 84000 / PFS 1ml Ref. No: 84001 GMDN: 45180
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.: 1828C04210505, whose original expiry date was 03/06/2023, 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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Registration Number: 144520204000

Diana Mochintra
General Manager

Date: 04/04/2024

ANNEX I - Applied Standards

Standard Number	Title
EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes
EN ISO 14971:2019	Medical devices - Application of risk management to medical devices
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 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 62366:2015 / AC:2020	Medical devices - Application of usability engineering to medical devices
EN ISO 15223-1:2021	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
EN 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 11138-1:2017	Sterilization of health care products — Biological indicators — Part 1: General requirements
EN ISO 11138-3:2017	Sterilization of health care products — Biological indicators — Part 3: Biological indicators for moist heat sterilization processes
ASTM F1929-15	Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
ASTM D4169-16	Standard Practice for Performance Testing of Shipping Containers and Systems
ASTM F88/F88M-15	Standard Test Method for Seal Strength of Flexible Barrier Materials
EN ISO 14644-1:2015	Cleanrooms and associated controlled environments — Part 1: Classification of air cleanliness by particle concentration
EN 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
EN ISO 14644-3:2019	Clean rooms and associated controlled environments - Test methods
EN ISO 14644-4:2022	Clean rooms and associated control environments - Design, construction and start - up
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
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