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-10
Manufacturer	:	SIDAPHARM P.C.
Facility Address	:	21, Stageiriti & 24, Em. Fili str., GR-543 52, Thessaloniki, Greece
Product	:	**SIDAPHARM** Ophthalmic Microsurgical Cannulas **Olie Medical** Ophthalmic Microsurgical Cannulas (Annex I) GMDN: 46705
Classification	:	IIa, according to Annex IX of Council Directive 93/42/EEC
Guidelines Applicable	:	MEDDEV 2.4/1 Rev. 9 - June 2010 Rule 6

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.
Medical Disposables
Head Offices: 21, Stageiriti & 24, Em. Fili str.
Thessaloniki GR-54352, Greece
Branch: 6, Laertou str., Kalamaria GR-55535, Greece
Tel: +30 2310 906660 - Fax: +30 2310 989846
VAT Reg. No.: EL997296038
Registration Number: 144520204000

Diana Mochintra
General Manager

Date: 04/04/2024

SIDAPHARM®
Ophthalmic & Medical Disposable Products

ANNEX I – Variations

Description	Ref. No
SIDAPHARM Ophthalmic Microsurgical Cannulas Cystotome Formed 25G	77006
SIDAPHARM Ophthalmic Microsurgical Cannulas Cystotome Formed 27G	77007
SIDAPHARM Ophthalmic Microsurgical Cannulas Cystotome Formed 30G	77008
SIDAPHARM Ophthalmic Microsurgical Cannulas Anterior Chamber Viscoelastic 23G	77081
SIDAPHARM Ophthalmic Microsurgical Cannulas Anterior Chamber Viscoelastic 25G	77104
SIDAPHARM Ophthalmic Microsurgical Cannulas Anterior Chamber Viscoelastic 27G	77082
SIDAPHARM Ophthalmic Microsurgical Cannulas Anterior Chamber Rycroft, 23G	77044
SIDAPHARM Ophthalmic Microsurgical Cannulas Anterior Chamber Rycroft, 25G	77001
SIDAPHARM Ophthalmic Microsurgical Cannulas Anterior Chamber Rycroft, 4mm, 27G	77003-1
SIDAPHARM Ophthalmic Microsurgical Cannulas Anterior Chamber Rycroft, 8mm, 27G	77056
SIDAPHARM Ophthalmic Microsurgical Cannulas Anterior Chamber Rycroft, 10mm, 27G	77003
SIDAPHARM Ophthalmic Microsurgical Cannulas Anterior Chamber Rycroft, 4mm, 30G	77046
SIDAPHARM Ophthalmic Microsurgical Cannulas Anterior Chamber Rycroft, 6mm, 30G	77004
SIDAPHARM Ophthalmic Microsurgical Cannulas Anterior Chamber Maintainer, 19G	77015
SIDAPHARM Ophthalmic Microsurgical Cannulas Anterior Chamber Maintainer, 20G	77016
SIDAPHARM Ophthalmic Microsurgical Cannulas Hydrodissection Angled, 23G	77062
SIDAPHARM Ophthalmic Microsurgical Cannulas Hydrodissection Angled, 25G	77010
SIDAPHARM Ophthalmic Microsurgical Cannulas Hydrodissection Angled, 27G	77012
SIDAPHARM Ophthalmic Microsurgical Cannulas Hydrodissection Angled, 30G	77013
SIDAPHARM Ophthalmic Microsurgical Cannulas Hydrodissection Curved, Horizontal Tip 27G	77014
SIDAPHARM Ophthalmic Microsurgical Cannulas Hydrodissection Curved, Vertical Tip 27G	77063
SIDAPHARM Ophthalmic Microsurgical Cannulas Hydrodissection J-shaped 25G	77067
SIDAPHARM Ophthalmic Microsurgical Cannulas Hydrodissection J-shaped 27G	77068
SIDAPHARM Ophthalmic Microsurgical Cannulas Capsule Polisher Cannula, 21G	77073
SIDAPHARM Ophthalmic Microsurgical Cannulas Capsule Polisher, 23G	77074
SIDAPHARM Ophthalmic Microsurgical Cannulas Capsule Polisher Silicon Tip 23G, 7mm tip	77070
SIDAPHARM Ophthalmic Microsurgical Cannulas Capsule Polisher Silicon Tip 23G, 9mm tip	77072
SIDAPHARM Ophthalmic Microsurgical Cannulas Anesthesia Cannula, Retrobulbar, 25G	77027
SIDAPHARM Ophthalmic Microsurgical Cannulas Anesthesia Cannula, Retrobulbar, 27G	77028
SIDAPHARM Ophthalmic Microsurgical Cannulas Anesthesia Subtenon 19G	77032
SIDAPHARM Ophthalmic Microsurgical Cannulas Anesthesia Peribulbar, 22mm, 25G	77030
SIDAPHARM Ophthalmic Microsurgical Cannulas Anesthesia Peribulbar, 32mm, 25G	77038
SIDAPHARM Ophthalmic Microsurgical Cannulas Irrigation & Aspiration Simcoe 20G	77022
SIDAPHARM Ophthalmic Microsurgical Cannulas Irrigation & Aspiration Simcoe 23G	77025
SIDAPHARM Ophthalmic Microsurgical Cannulas Lacrimal Cannula, 26G	77021
SIDAPHARM Ophthalmic Microsurgical Cannulas Lacrimal Intubation Set, Straight Tip 17.5cm, 23G	77083
SIDAPHARM Ophthalmic Microsurgical Cannulas Lacrimal Intubation Set, Olive Tip 11cm	77084
Olie Medical Ophthalmic Microsurgical Cannulas Cystotome Formed 25G	77006
Olie Medical Ophthalmic Microsurgical Cannulas Cystotome Formed 27G	77007
Olie Medical Ophthalmic Microsurgical Cannulas Anterior Chamber Viscoelastic 27G	77082
Olie Medical Ophthalmic Microsurgical Cannulas Anterior Chamber Rycroft, 6mm, 30G	77004
Olie Medical Ophthalmic Microsurgical Cannulas Hydrodissection Angled, 25G	77010
Olie Medical Ophthalmic Microsurgical Cannulas Hydrodissection Angled, 30G	77013
Olie Medical Ophthalmic Microsurgical Cannulas Hydrodissection Curved, Horizontal Tip 27G	77014
Olie Medical Ophthalmic Microsurgical Cannulas Anesthesia Subtenon 19G	77032
Olie Medical Ophthalmic Microsurgical Cannulas Irrigation & Aspiration Simcoe 23G	77025
Olie Medical Ophthalmic Microsurgical Cannulas Lacrimal Cannula, 26G	77021

ANNEX II – 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 20417:2021	Medical devices - Information to be supplied by the manufacturer
ISO/TR 24971:2020	Medical devices - Guidance on the application of ISO 14971
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 ISO 10993-5:2009	Biological Evaluation of Medical Devices - Part 5: Tests for In vitro Cytotoxicity
EN ISO 10993-7:2008+ A1:2022	Biological Evaluation of Medical Devices Part 7: Ethylene Oxide Sterilization Residuals- Amendment 1: Applicability of allowable limits for neonates and infants
EN ISO 10993-10:2023	Biological evaluation of medical devices - Part 10: Tests for skin sensitization
EN ISO 10993-11:2018	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
EN ISO 10993-18:2020	Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process
EN ISO 10993-23:2021	Biological evaluation of medical devices - Part 23: Tests for irritation
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 11135:2014	Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices
EN ISO 11138-1:2017	Sterilization of health care products - Biological indicators - Part 1: General requirements
EN ISO 11138-2:2017	Sterilization of health care products - Biological indicators - Part 2: Biological indicators for ethylene oxide sterilization processes
EN ISO 11737-1:2018	Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products
EN ISO 11737-2:2018	Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products
EN ISO 11140-1:2014	Sterilization of health care products - Chemical indicators - Part 1: General requirements

EN 868-5:2018	Packaging for terminally sterilized medical devices - Part 5: Sealable pouches and reels of porous materials and plastic film construction - Requirements and test methods
EN ISO 2578:2000	Plastics - Determination of time-temperature limits after prolonged exposure to heat
ASTM F1929-15	Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
ASTM F2096	Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization
ASTM F88/F88M	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	Cleanrooms and associated controlled environments - Part 3: Test methods
ISO 9626:2016	Stainless steel needle tubing for the manufacture of medical devices
ISO 6009:2016	Hypodermic needles for single use - Color coding for identification
EN ISO 80369-7:2021	Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications
EN ISO 7864:2016	Sterile hypodermic needles for single use - Requirements and test methods
E.P.	European Pharmacopoeia

21, Stageiriti & 24, Em. Fili str., Thessaloniki 54352, Greece
Tel. +30 2310906660 Fax: +30 2310989846
info@sidapharm.gr