

EC DECLARATION OF CONFORMITY

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

Reference No : 1828C-09
Manufacturer : SIDAPHARM P.C.
Facility Address : 21, Stageiriti & 24, Em. Fili str., GR 543 52, Thessaloniki, Greece
Product : **SIDAPHARM** Ophthalmic Microsurgical Knives (Annex I)
GMDN: 46741
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.
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Registration Number: 144520204000

Diana Mochintra
General Manager

Date: 04/04/2024

ANNEX I - Variations

Description	Ref. No
SIDAPHARM Ophthalmic Microsurgical Knives Slit 1.4 mm	62056
SIDAPHARM Ophthalmic Microsurgical Knives Slit 1.6 mm	62057
SIDAPHARM Ophthalmic Microsurgical Knives Slit 1.8 mm	62058
SIDAPHARM Ophthalmic Microsurgical Knives Slit 2.0 mm	62059
SIDAPHARM Ophthalmic Microsurgical Knives Slit 2.2 mm	62016
SIDAPHARM Ophthalmic Microsurgical Knives Slit 2.4 mm	62017
SIDAPHARM Ophthalmic Microsurgical Knives Slit 2.6 mm	62052
SIDAPHARM Ophthalmic Microsurgical Knives Slit 2.75 mm	62018-1
SIDAPHARM Ophthalmic Microsurgical Knives Slit 2.80 mm	62018
SIDAPHARM Ophthalmic Microsurgical Knives Slit 3.0 mm	62019
SIDAPHARM Ophthalmic Microsurgical Knives Slit 3.2 mm	62020
SIDAPHARM Ophthalmic Microsurgical Knives Slit Double Bevel 1.4 mm	62056-DB
SIDAPHARM Ophthalmic Microsurgical Knives Slit Double Bevel 1.6 mm	62057-DB
SIDAPHARM Ophthalmic Microsurgical Knives Slit Double Bevel 1.8 mm	62058-DB
SIDAPHARM Ophthalmic Microsurgical Knives Slit Double Bevel 2.0 mm	62059-DB
SIDAPHARM Ophthalmic Microsurgical Knives Slit Double Bevel 2.2 mm	62016-DB
SIDAPHARM Ophthalmic Microsurgical Knives Slit Double Bevel 2.4 mm	62017-DB
SIDAPHARM Ophthalmic Microsurgical Knives Slit Double Bevel 2.6 mm	62052-DB
SIDAPHARM Ophthalmic Microsurgical Knives Slit Double Bevel 2.75 mm	620181-DB
SIDAPHARM Ophthalmic Microsurgical Knives Slit Double Bevel 2.80 mm	62018-DB
SIDAPHARM Ophthalmic Microsurgical Knives Slit Double Bevel 3.00 mm	62019-DB
SIDAPHARM Ophthalmic Microsurgical Knives Slit Double Bevel 3.20 mm	62020-DB
SIDAPHARM Ophthalmic Microsurgical Knives Stab 15 deg	62000
SIDAPHARM Ophthalmic Microsurgical Knives Stab 22.5 deg	62021
SIDAPHARM Ophthalmic Microsurgical Knives Stab 30 deg	62001
SIDAPHARM Ophthalmic Microsurgical Knives Stab 45 deg	62002
SIDAPHARM Ophthalmic Microsurgical Knives Crescent Bevel Up	62003
SIDAPHARM Ophthalmic Microsurgical Knives Crescent Straight	62003-1
SIDAPHARM Ophthalmic Microsurgical Knives MVR 19G	62004
SIDAPHARM Ophthalmic Microsurgical Knives MVR 20G	62005
SIDAPHARM Ophthalmic Microsurgical Knives MVR 23G	62007
SIDAPHARM Ophthalmic Microsurgical Knives MVR 19G Angled	62009
SIDAPHARM Ophthalmic Microsurgical Knives MVR 20G Angled	62010
SIDAPHARM Ophthalmic Microsurgical Knives MVR 23G Angled	62012
SIDAPHARM Ophthalmic Microsurgical Knives Implant Angled 5.2 mm	62027
SIDAPHARM Ophthalmic Microsurgical Knives Implant Angled 5.5 mm	62055
SIDAPHARM Ophthalmic Microsurgical Knives Slit 1.2 mm non-Sterile	62060-NS
SIDAPHARM Ophthalmic Microsurgical Knives Slit 1.4 mm non-Sterile	62056-NS
SIDAPHARM Ophthalmic Microsurgical Knives Slit 1.6 mm non-Sterile	62057-NS
SIDAPHARM Ophthalmic Microsurgical Knives Slit 1.8 mm non-Sterile	62058-NS
SIDAPHARM Ophthalmic Microsurgical Knives Slit 2.0 mm non-Sterile	62059-NS
SIDAPHARM Ophthalmic Microsurgical Knives Slit 2.2 mm non-Sterile	62016-NS
SIDAPHARM Ophthalmic Microsurgical Knives Slit 2.4 mm non-Sterile	62017-NS
SIDAPHARM Ophthalmic Microsurgical Knives Slit 2.6 mm non-Sterile	62052-NS
SIDAPHARM Ophthalmic Microsurgical Knives Slit 2.75 mm non-Sterile	62018-1NS
SIDAPHARM Ophthalmic Microsurgical Knives Slit 2.8 mm non-Sterile	62018-NS
SIDAPHARM Ophthalmic Microsurgical Knives Slit 3.0 mm non-Sterile	62019-NS
SIDAPHARM Ophthalmic Microsurgical Knives Slit 3.2 mm non-Sterile	62020-NS

SIDAPHARM Ophthalmic Microsurgical Knives Slit Double Bevel 1.2 mm non-Sterile	62060-DBNS
SIDAPHARM Ophthalmic Microsurgical Knives Slit Double Bevel 1.4 mm non-Sterile	62056-DBNS
SIDAPHARM Ophthalmic Microsurgical Knives Slit Double Bevel 1.6 mm non-Sterile	62057-DBNS
SIDAPHARM Ophthalmic Microsurgical Knives Slit Double Bevel 1.8 mm non-Sterile	62058-DBNS
SIDAPHARM Ophthalmic Microsurgical Knives Slit Double Bevel 2.0 mm non-Sterile	62059-DBNS
SIDAPHARM Ophthalmic Microsurgical Knives Slit Double Bevel 2.2 mm non-Sterile	62016-DBNS
SIDAPHARM Ophthalmic Microsurgical Knives Slit Double Bevel 2.4 mm non-Sterile	62017-DBNS
SIDAPHARM Ophthalmic Microsurgical Knives Slit Double Bevel 2.6 mm non-Sterile	62052-DBNS
SIDAPHARM Ophthalmic Microsurgical Knives Slit Double Bevel 2.75 mm non-Sterile	620181-DBNS
SIDAPHARM Ophthalmic Microsurgical Knives Slit Double Bevel 2.8 mm non-Sterile	62018-DBNS
SIDAPHARM Ophthalmic Microsurgical Knives Slit Double Bevel 3.0 mm non-Sterile	62019-DBNS
SIDAPHARM Ophthalmic Microsurgical Knives Slit Double Bevel 3.2 mm non-Sterile	62020-DBNS
SIDAPHARM Ophthalmic Microsurgical Knives Stab 15 deg non-Sterile	62000-NS
SIDAPHARM Ophthalmic Microsurgical Knives Stab 22.5 deg non-Sterile	62021-NS
SIDAPHARM Ophthalmic Microsurgical Knives Stab 30 deg non-Sterile	62001-NS
SIDAPHARM Ophthalmic Microsurgical Knives Stab 45 Deg Non-Sterile	62002-NS
SIDAPHARM Ophthalmic Microsurgical Knives Crescent Bevel Up Non-Sterile	62003-NS
SIDAPHARM Ophthalmic Microsurgical Knives Crescent Straight Non-Sterile	62003-1NS
SIDAPHARM Ophthalmic Microsurgical Knives MVR 19G non-Sterile	62004-NS
SIDAPHARM Ophthalmic Microsurgical Knives MVR 20G non-Sterile	62005-NS
SIDAPHARM Ophthalmic Microsurgical Knives MVR 23G non-Sterile	62007-NS
SIDAPHARM Ophthalmic Microsurgical Knives MVR 19G Angled non-Sterile	62009-NS
SIDAPHARM Ophthalmic Microsurgical Knives MVR 20G Angled non-Sterile	62010-NS
SIDAPHARM Ophthalmic Microsurgical Knives MVR 23G Angled non-Sterile	62012-NS
SIDAPHARM Ophthalmic Microsurgical Knives Slit 1.2 mm Safety	62060-SF
SIDAPHARM Ophthalmic Microsurgical Knives Slit 1.4 mm Safety	62056-SF
SIDAPHARM Ophthalmic Microsurgical Knives Slit 1.6 mm Safety	62057-SF
SIDAPHARM Ophthalmic Microsurgical Knives Slit 1.8 mm Safety	62058-SF
SIDAPHARM Ophthalmic Microsurgical Knives Slit 2.0 mm Safety	62059-SF
SIDAPHARM Ophthalmic Microsurgical Knives Slit 2.2 mm Safety	62016-SF
SIDAPHARM Ophthalmic Microsurgical Knives Slit 2.4 mm Safety	62017-SF
SIDAPHARM Ophthalmic Microsurgical Knives Slit 2.6 mm Safety	62052-SF
SIDAPHARM Ophthalmic Microsurgical Knives Slit 2.75 mm Safety	62018-1SF
SIDAPHARM Ophthalmic Microsurgical Knives Slit 2.8 mm Safety	62018-SF
SIDAPHARM Ophthalmic Microsurgical Knives Slit 3.0 mm Safety	62019-SF
SIDAPHARM Ophthalmic Microsurgical Knives Slit 3.2 mm Safety	62020-SF
SIDAPHARM Ophthalmic Microsurgical Knives Slit Double Bevel 1.2 mm Safety	62060-DBSF
SIDAPHARM Ophthalmic Microsurgical Knives Slit Double Bevel 1.4 mm Safety	62056-DBSF
SIDAPHARM Ophthalmic Microsurgical Knives Slit Double Bevel 1.6 mm Safety	62057-DBSF
SIDAPHARM Ophthalmic Microsurgical Knives Slit Double Bevel 1.8 mm Safety	62058-DBSF
SIDAPHARM Ophthalmic Microsurgical Knives Slit Double Bevel 2.0 mm Safety	62059-DBSF
SIDAPHARM Ophthalmic Microsurgical Knives Slit Double Bevel 2.2 mm Safety	62016-DBSF
SIDAPHARM Ophthalmic Microsurgical Knives Slit Double Bevel 2.4 mm Safety	62017-DBSF
SIDAPHARM Ophthalmic Microsurgical Knives Slit Double Bevel 2.6 mm Safety	62052-DBSF
SIDAPHARM Ophthalmic Microsurgical Knives Slit Double Bevel 2.75 mm Safety	620181-DBSF
SIDAPHARM Ophthalmic Microsurgical Knives Slit Double Bevel 2.8 mm Safety	62018-DBSF
SIDAPHARM Ophthalmic Microsurgical Knives Slit Double Bevel 3.0 mm Safety	62019-DBSF
SIDAPHARM Ophthalmic Microsurgical Knives Slit Double Bevel 3.2 mm Safety	62020-DBSF
SIDAPHARM Ophthalmic Microsurgical Knives Stab 15 deg Safety	62000-SF
SIDAPHARM Ophthalmic Microsurgical Knives Stab 22.5 deg Safety	62021-SF
SIDAPHARM Ophthalmic Microsurgical Knives Stab 30 deg Safety	62001-SF

SIDAPHARM Ophthalmic Microsurgical Knives Stab 45 deg Safety	62002-SF
SIDAPHARM Ophthalmic Microsurgical Knives Crescent Bevel Up Safety	62003-SF
SIDAPHARM Ophthalmic Microsurgical Knives Crescent Straight Safety	62003-1SF
SIDAPHARM Ophthalmic Microsurgical Knives MVR 19G Safety	62004-SF
SIDAPHARM Ophthalmic Microsurgical Knives MVR 20G Safety	62005-SF
SIDAPHARM Ophthalmic Microsurgical Knives MVR 23G Safety	62007-SF
SIDAPHARM Ophthalmic Microsurgical Knives MVR 19G Angled Safety	62009-SF
SIDAPHARM Ophthalmic Microsurgical Knives MVR 20G Angled Safety	62010-SF
SIDAPHARM Ophthalmic Microsurgical Knives MVR 23G Angled Safety	62012-SF
SIDAPHARM Ophthalmic Microsurgical Knives Slit 1.2 mm Safety Non-Sterile	62060-SFNS
SIDAPHARM Ophthalmic Microsurgical Knives Slit 1.4 mm Safety Non-Sterile	62056-SFNS
SIDAPHARM Ophthalmic Microsurgical Knives Slit 1.6 mm Safety Non-Sterile	62057-SFNS
SIDAPHARM Ophthalmic Microsurgical Knives Slit 1.8 mm Safety Non-Sterile	62058-SFNS
SIDAPHARM Ophthalmic Microsurgical Knives Slit 2.0 Mm Safety Non-Sterile	62059-SFNS
SIDAPHARM Ophthalmic Microsurgical Knives Slit 2.2 Mm Safety Non-Sterile	62016-SFNS
SIDAPHARM Ophthalmic Microsurgical Knives Slit 2.4 mm Safety Non-Sterile	62017-SFNS
SIDAPHARM Ophthalmic Microsurgical Knives Slit 2.6 Mm Safety Non-Sterile	62052-SFNS
SIDAPHARM Ophthalmic Microsurgical Knives Slit 2.75 Mm Safety Non-Sterile	62018-1SFNS
SIDAPHARM Ophthalmic Microsurgical Knives Slit 2.8 mm Safety Non-Sterile	62018-SFNS
SIDAPHARM Ophthalmic Microsurgical Knives Slit 3.0 mm Safety Non-Sterile	62019-SFNS
SIDAPHARM Ophthalmic Microsurgical Knives Slit 3.2 mm Safety Non-Sterile	62020-SFNS
SIDAPHARM Ophthalmic Microsurgical Knives Slit Double Bevel 1.6 mm Safety Non-Sterile	62057-DBSFNS
SIDAPHARM Ophthalmic Microsurgical Knives Slit Double Bevel 1.8 mm Safety Non-Sterile	62058-DBSFNS
SIDAPHARM Ophthalmic Microsurgical Knives Slit Double Bevel 2.0 mm Safety Non-Sterile	62059-DBSFNS
SIDAPHARM Ophthalmic Microsurgical Knives Slit Double Bevel 2.2 mm Safety Non-Sterile	62016-DBSFNS
SIDAPHARM Ophthalmic Microsurgical Knives Slit Double Bevel 2.4 mm Safety Non-Sterile	62017-DBSFNS
SIDAPHARM Ophthalmic Microsurgical Knives Slit Double Bevel 2.6 mm Safety Non-Sterile	62052-DBSFNS
SIDAPHARM Ophthalmic Microsurgical Knives Slit Double Bevel 2.75 mm Safety Non-Sterile	620181-DBSFNS
SIDAPHARM Ophthalmic Microsurgical Knives Slit Double Bevel 2.8 mm Safety Non-Sterile	62018-DBSFNS
SIDAPHARM Ophthalmic Microsurgical Knives Slit Double Bevel 3.0 Mm Safety Non-Sterile	62019-DBSFNS
SIDAPHARM Ophthalmic Microsurgical Knives Slit Double Bevel 3.2 Mm Safety Non-Sterile	62020-DBSFNS
SIDAPHARM Ophthalmic Microsurgical Knives Stab 15 deg Safety non-Sterile	62000-SFNS
SIDAPHARM Ophthalmic Microsurgical Knives Stab 22.5 deg Safety non-Sterile	62021-SFNS
SIDAPHARM Ophthalmic Microsurgical Knives Stab 30 deg Safety non-Sterile	62001-SFNS
SIDAPHARM Ophthalmic Microsurgical Knives Stab 45 deg Safety non-Sterile	62002-SFNS
SIDAPHARM Ophthalmic Microsurgical Knives Crescent Bevel Up Safety Non-Sterile	62003-SFNS
SIDAPHARM Ophthalmic Microsurgical Knives Crescent Straight Safety Non-Sterile	62003-1SFNS
SIDAPHARM Ophthalmic Microsurgical Knives MVR 19G Safety Non-Sterile	62004-SFNS
SIDAPHARM Ophthalmic Microsurgical Knives MVR 20G Safety Non-Sterile	62005-SFNS
SIDAPHARM Ophthalmic Microsurgical Knives MVR 23G Safety Non-Sterile	62007-SFNS
SIDAPHARM Ophthalmic Microsurgical Knives MVR 19G Angled Safety Non-Sterile	62009-SFNS
SIDAPHARM Ophthalmic Microsurgical Knives MVR 20G Angled Safety Non-Sterile	62010-SFNS
SIDAPHARM Ophthalmic Microsurgical Knives MVR 23G Angled Safety Non-Sterile	62012-SFNS

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 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 10993-7:2008+ AC: 2009	Biological Evaluation of Medical Devices-Part 7: Ethylene oxide sterilization residuals
EN ISO 11135:2014+A1:2019	Sterilization of health-care products. Ethylene oxide. Requirements for the development, validation and routine control of a sterilization process for 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 10993-11:2018	Biological Evaluation of Medical Devices-Part11: Tests For systemic toxicity
EN ISO 10993-10:2010	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.
EN ISO 10993-23:2021	Biological evaluation of medical devices - Part 23: Tests for irritation.
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
ISTA 2A	General simulation performance tests- Packaged-Products for Parcel Delivery System Shipment weighing 68kg (150 lb) or less
ISO 11138-2:2017	Sterilization of health care products - Biological indicators - Part 2: Biological indicators for ethylene oxide sterilization processes
ASTM F 1980-16	Standard for Accelerated ageing of sterile barrier system of medical device
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