



ΕΘΝΙΚΟ ΚΕΝΤΡΟ ΑΞΙΟΛΟΓΗΣΗΣ
ΤΗΣ ΠΟΙΟΤΗΤΑΣ & ΤΕΧΝΟΛΟΓΙΑΣ
ΣΤΗΝ ΥΓΕΙΑ Α.Ε.

NATIONAL EVALUATION CENTER
OF QUALITY & TECHNOLOGY
IN HEALTH S.A.

ΠΙΣΤΟΠΟΙΗΤΙΚΟ ΕΚ / EC CERTIFICATE

ΠΛΗΡΕΣ ΣΥΣΤΗΜΑ ΔΙΑΣΦΑΛΙΣΗΣ ΠΟΙΟΤΗΤΑΣ / FULL QUALITY ASSURANCE SYSTEM

Πιστοποιείται ότι ο παρακάτω αναφερόμενος κατασκευαστής έχει καθιερώσει και εφαρμόζει πλήρες σύστημα διασφάλισης της ποιότητας σύμφωνα με τις απαιτήσεις της Οδηγίας 93/42/ΕΟΚ, Παράρτημα II (εξαιρουμένου του σημείου 4) και της ενσωμάτωσης της στην ελληνική νομοθεσία, για το σχεδιασμό, την κατασκευή και τον τελικό έλεγχο των προϊόντων που αναφέρονται στο παρόν πιστοποιητικό. Το πιστοποιητικό υπόκειται στους όρους και τις προϋποθέσεις που αναγράφονται στην επόμενη σελίδα. Οποιοσδήποτε σημαντικές αλλαγές στο σχεδιασμό ή την κατασκευή μπορεί να καταστήσουν το πιστοποιητικό άκυρο.

We hereby certify that the under mentioned manufacturer has established and maintains a full quality assurance system according to the requirements of Directive 93/42/EEC, Annex II (with the exemption of section 4) and its transposition in Greek legislation, for the design, manufacture and final inspection of the products mentioned in this certificate.

The certificate is subject to terms and conditions overleaf.

Any significant changes in design or manufacture may render this certificate invalid.

Αριθμός Πιστοποιητικού / Certificate Number: 3050201023M

Το παρόν εκδίδεται προς αντικατάσταση του υπ' αριθ. 3050201023AD1 πιστοποιητικού.
The present is issued to replace certificate nr 3050201023AD1.

Κατασκευαστής: **SIDAPHARM I.K.E., "SIDAPHARM".**

Manufacturer: **SIDAPHARM P.C., "SIDAPHARM".**

Εγκατάσταση: **ΣΤΑΓΕΙΡΙΤΗ 21 & ΕΜ. ΦΙΛΗ 24, 543 52 ΘΕΣΣΑΛΟΝΙΚΗ.**

Facility: **21, STAGEIRITI & 24, EM. FILI STR., 543 52 THESSALONIKI GREECE.**

Προϊόντα: **ΩΣ ΕΧΟΥΝ ΣΤΟ ΠΑΡΑΡΤΗΜΑ.**

Products: **AS LISTED IN ANNEX.**

Κατηγοριοποίηση Προϊόντων: **ΩΣ ΕΧΕΙ ΣΤΟ ΠΑΡΑΡΤΗΜΑ.**

Devices Classification: **AS LISTED IN ANNEX.**

Ημερομηνία πρώτης έκδοσης: **04/06/2018**

First issue date: **04/06/2018**

Ημερομηνία τρέχουσας έκδοσης: **25/05/2021**

Current issue date: **25/05/2021**

Ισχύει μέχρι: **03/06/2023**

Valid until: **03/06/2023**

Έκθεση επιθεώρησης: **200081023**

Audit report: **200081023**

Digitally signed by Pereteatco Alina

Date: 2021.10.08 09:57:11 EEST

Reason: MoldSign Signature

Location: Moldova



ΠΙΚΡΟΥ - ΜΩΡΑΪΤΑΚΗ ΕΛΕΥΘΕΡΙΑ, Πρόεδρος & Διευθύνουσα Σύμβουλος
PIKROU - MORAITAKI ELEFTHERIA, President & Managing Director

Το Εθνικό Κέντρο Αξιολόγησης της Ποιότητας και Τεχνολογίας στην Υγεία (ΕΚΑΠΤΥ) είναι Κοινοποιημένος Οργανισμός σύμφωνα με την Οδηγία 93/42/ΕΟΚ περί των ιατροτεχνολογικών προϊόντων, με αριθμό αναγνώρισης 0653.
National Evaluation Center of Quality & Technology in Health S.A. (EKAPTY) is a Notified body according to Council Directive 93/42/EEC concerning medical devices, with identification number 0653.



**ΕΘΝΙΚΟ ΚΕΝΤΡΟ ΑΞΙΟΛΟΓΗΣΗΣ
ΤΗΣ ΠΟΙΟΤΗΤΑΣ & ΤΕΧΝΟΛΟΓΙΑΣ
ΣΤΗΝ ΥΓΕΙΑ Α.Ε.**

NATIONAL EVALUATION CENTER
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IN HEALTH S.A.

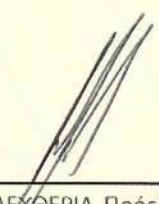
**ΠΑΡΑΡΤΗΜΑ ΤΟΥ ΥΠ. ΑΡΙΘΜ. 3050201023Μ ΠΙΣΤΟΠΟΙΗΤΙΚΟΥ /
ANNEX Nr. 3050201023M CERTIFICATE.**

ΚΑΤΗΓΟΡΙΑ / CLASS: Is

	ΙΑΤΡΟΤΕΧΝΟΛΟΓΙΚΟ ΠΡΟΪΟΝ / MEDICAL DEVICE	ΤΥΠΟΣ / TRADE NAME
1.	ΡΙΝΙΚΑ ΕΠΙΘΕΜΑΤΑ/ PVA NASAL DRESSINGS.	SIDA-CEL ENT.
2.	ΧΕΙΡΟΥΡΓΙΚΕΣ ΠΟΔΙΕΣ / SURGICAL GOWNS.	SIDAPHARM STERILE SURGICAL GOWNS, SIDAPHARM STERILE SURGICAL GOWNS WITH TOWELS.
3.	ΟΦΘΑΛΜΟΛΟΓΙΚΑ ΠΕΔΙΑ / OPHTHALMIC DRAPES.	SIDAPHARM STERILE OPHTHALMIC DRAPES.
4.	ΟΦΘΑΛΜΙΚΑ ΤΡΙΓΩΝΑΚΙΑ PVA / PVA EYE SPEARS.	-SIDA-SPEARS. -OLIE MEDICAL PVA EYE SPEARS.
5.	ΧΕΙΡΟΥΡΓΙΚΑ ΠΕΔΙΑ / SURGICAL DRAPES.	SURGICAL DRAPE, MAYO SURGICAL COVER, SURGICAL DRAPE C-ARM, MICROSCOPE DRAPE, ANGIOGRAPHY DRAPE, ARTHROSCOPY DRAPE, C-SECTION DRAPE, FEMORAL & RADIAL ANGIOGRAPHY DRAPE.
6.	ΟΦΘΑΛΜΟΛΟΓΙΚΕΣ ΤΑΙΝΙΕΣ ΦΛΟΥΟΡΕΣΚΕΪΝΗΣ/ FLUORESCEIN SODIUM OPHTHALMIC STRIPS.	SIDA-FLUORO.

ΚΑΤΗΓΟΡΙΑ / CLASS: IIa

	ΙΑΤΡΟΤΕΧΝΟΛΟΓΙΚΟ ΠΡΟΪΟΝ / MEDICAL DEVICE	ΤΥΠΟΣ / TRADE NAME
7.	ΔΙΑΛΥΤΗ ΑΙΜΟΣΤΑΤΙΚΗ ΓΑΖΑ/ SOLUBLE HEMOSTATIC GAUZE.	- SIDA-CEL. - CLOTGENE


ΠΙΚΡΟΥ - ΜΩΡΑΪΤΑΚΗ ΕΛΕΥΘΕΡΙΑ, Πρόεδρος & Διευθύνουσα Σύμβουλος
PIKROU - MORAITAKI ELEFThERIA, President & Managing Director

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**ΠΑΡΑΡΤΗΜΑ ΤΟΥ ΥΠ. ΑΡΙΘΜ. 3050201023Μ ΠΙΣΤΟΠΟΙΗΤΙΚΟΥ /
ANNEX Nr. 3050201023M CERTIFICATE.**

ΚΑΤΗΓΟΡΙΑ / CLASS IIb

	ΙΑΤΡΟΤΕΧΝΟΛΟΓΙΚΟ ΠΡΟΪΟΝ / MEDICAL DEVICE	ΤΥΠΟΣ / TRADE NAME
8	ΕΝΔΟΦΑΚΟΙ / INTRAOCULAR LENSES: - ΥΔΡΟΦΟΒΟΙ ΕΝΔΟΦΑΚΟΙ / HYDROPHOBIC INTRAOCULAR LENSES. - ΥΔΡΟΦΙΛΟΙ ΕΝΔΟΦΑΚΟΙ / HYDROPHILIC INTRAOCULAR LENSES. - ΕΝΔΟΦΑΚΟΙ PMMA / PMMA INTRAOCULAR LENSES.	 -SIDA-LENS / HYDROPHOBIC ONE PIECE ACRYLIC FOLDABLE INTRAOCULAR LENSES. Ref.Codes: SDHB, SDHBY, SDHB6130, SDHB6130S. -CREDENTIALIA X/HYDROPHOBIC ONE PIECE ACRYLIC FOLDABLE INTRAOCULAR LENSES Ref.Codes: SDHB, SDHBY, SDHB6130, SDHB6130S. -ORIZON / PRELOADED HYDROPHOBIC ONE PIECE ACRYLIC FOLDABLE INTRAOCULAR LENSES Ref. Codes: SDHBP, SDHBPY. -CREDENTIALIA PLUS/PRELOADED HYDROPHOBIC ONE PIECE ACRYLIC FOLDABLE INTRAOCULAR LENSES. Ref.Codes: SDHBP, SDHBPY. - SIDA-LENS / HYDROPHILIC ONE PIECE ACRYLIC FOLDABLE INTRAOCULAR LENSES. Ref. Codes: SDA, SDYA, SDA4, SDAC, SDACY. - CREDENTIALIA/HYDROPHILIC ONE PIECE ACRYLIC FOLDABLE INTRAOCULAR LENSES Ref.Codes: SDA, SDYA, SDA4, SDAC, SDACY. - SIDA-LENS / PMMA INTRAOCULAR LENSES. Ref. Codes: SDANT, SDHS, SDALP.



ΠΙΚΡΟΥ - ΜΩΡΑΪΤΑΚΗ ΕΛΕΥΘΕΡΙΑ, Πρόεδρος & Διευθύνουσα Σύμβουλος
PIKROU - MORAITAKI ELEFThERIA, President & Managing Director

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ΟΡΟΙ & ΠΡΟΫΠΟΘΕΣΕΙΣ / TERMS & CONDITIONS

1. Για αποστειρωμένα προϊόντα κατηγορίας I, η πιστοποίηση αφορά μόνο τα θέματα επίτευξης και διατήρησης της αποστείρωσης.
For class I sterile products, the certificate covers only the aspects of manufacture concerned with securing and maintaining sterile conditions.
2. Για προϊόντα κατηγορίας I με λειτουργία μέτρησης, η πιστοποίηση αφορά μόνο τα θέματα συμμόρφωσης των προϊόντων προς τις μετρολογικές απαιτήσεις.
For Class I devices with a measuring function the certificate covers only the aspects of manufacture concerned with the conformity of the products with metrological requirements.
3. Για προϊόντα κατηγορίας III, είναι απαραίτητο ένα συμπληρωματικό πιστοποιητικό Εξέτασης Σχεδιασμού σύμφωνα με τις απαιτήσεις της Οδηγίας 93/42/ΕΟΚ, Παράρτημα II (σημείο 4).
For class III products an additional Design Examination certificate is required according to the requirements of Annex II 93/42/EEC (section 4).
4. Το πιστοποιητικό ισχύει μόνο για τα προϊόντα και τις εγκαταστάσεις που αναφέρονται.
The certificate is valid only for the products and the facilities mentioned.
5. Θα πραγματοποιούνται περιοδικές επιθεωρήσεις επιτήρησης όπως αναφέρεται στην Οδηγία 93/42/ΕΟΚ, με σκοπό να επαληθεύεται ότι ο κατασκευαστής διατηρεί και εφαρμόζει το σύστημα ποιότητας.
Periodical surveillance as referred in 93/42/EEC will be held in order to verify that the manufacturer maintains and applies the quality system.
6. Όταν τηρούνται τα ανωτέρω, ο κατασκευαστής μπορεί να συντάσσει δήλωση συμμόρφωσης ΕΚ και να επιθέτει τη σήμανση CE 0653 στα καλυπτόμενα προϊόντα.
When meeting with the terms and conditions above, the manufacturer may draw up an EC declaration of conformity and legally affix the CE 0653 mark.


ΠΙΚΡΟΥ - ΜΩΡΑΪΤΑΚΗ ΕΛΕΥΘΕΡΙΑ, Πρόεδρος & Διευθύνουσα Σύμβουλος
PIKROU - MORAITAKI ELEFThERIA, President & Managing Director

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National Evaluation Center of Quality & Technology in Health S.A. (EKAPTY) is a Notified body according to Council Directive 93/42/EEC concerning medical devices, with identification number 0653.



**ΕΘΝΙΚΟ ΚΕΝΤΡΟ ΑΞΙΟΛΟΓΗΣΗΣ
ΤΗΣ ΠΟΙΟΤΗΤΑΣ & ΤΕΧΝΟΛΟΓΙΑΣ
ΣΤΗΝ ΥΓΕΙΑ Α.Ε.**

**NATIONAL EVALUATION CENTER
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IN HEALTH S.A.**

ΠΙΣΤΟΠΟΙΗΤΙΚΟ ΕΚ / EC CERTIFICATE

ΠΛΗΡΕΣ ΣΥΣΤΗΜΑ ΔΙΑΣΦΑΛΙΣΗΣ ΠΟΙΟΤΗΤΑΣ / FULL QUALITY ASSURANCE SYSTEM

Πιστοποιείται ότι ο παρακάτω αναφερόμενος κατασκευαστής έχει καθιερώσει και εφαρμόζει πλήρες σύστημα διασφάλισης της ποιότητας σύμφωνα με τις απαιτήσεις της Οδηγίας 93/42/ΕΟΚ, Παράρτημα ΙΙ (εξαιρουμένου του σημείου 4) και της ενσωμάτωσης της στην ελληνική νομοθεσία, για το σχεδιασμό, την κατασκευή και τον τελικό έλεγχο των προϊόντων που αναφέρονται στο παρόν πιστοποιητικό. Το πιστοποιητικό υπόκειται στους όρους και τις προϋποθέσεις που αναγράφονται στην επόμενη σελίδα. Οποιαδήποτε σημαντικές αλλαγές στο σχεδιασμό ή την κατασκευή μπορεί να καταστήσουν το πιστοποιητικό άκυρο.

We hereby certify that the under mentioned manufacturer has established and maintains a full quality assurance system according to the requirements of Directive 93/42/EEC, Annex II (with the exemption of section 4) and its transposition in Greek legislation, for the design, manufacture and final inspection of the products mentioned in this certificate. The certificate is subject to terms and conditions overleaf. Any significant changes in design or manufacture may render this certificate invalid.

Αριθμός Πιστοποιητικού / Certificate Number: 305081023

Το παρόν εκδίδεται προς αντικατάσταση του υπ' αριθ. 305071023 πιστοποιητικού.
The present is issued to replace certificate nr 305071023.

Κατασκευαστής: **SIDAPHARM I.K.E., "SIDAPHARM"**

Manufacturer: **SIDAPHARM P.C., "SIDAPHARM"**

Εγκατάσταση: **ΣΤΑΓΕΙΡΙΤΗ 21 & ΕΜ. ΦΙΛΗ 24, 543 52 ΘΕΣΣΑΛΟΝΙΚΗ.**

Facility: **21, STAGEIRITI & 24, EM. FILI STR., 543 52 THESSALONIKI GREECE.**

Προϊόντα: **ΩΣ ΕΧΟΥΝ ΣΤΟ ΠΑΡΑΡΤΗΜΑ Ι**

Products: **AS LISTED IN ANNEX I**

Κατηγοριοποίηση Προϊόντων: **ΩΣ ΕΧΟΥΝ ΣΤΟ ΠΑΡΑΡΤΗΜΑ Ι**

Devices Classification: **AS LISTED IN ANNEX I**

Ημερομηνία πρώτης έκδοσης: **04/06/2018**
First issue date:

Ημερομηνία τρέχουσας έκδοσης: **10/01/2019**
Current issue date:

Ισχύει μέχρι: **03/06/2023**
Valid until:

Έκθεση επιθεώρησης: **200061023**
Audit report:

Σ. ΠΟΡΑΒΟΣ, Διευθύνων Σύμβουλος
S. PORAVOS, Managing Director

Κ. ΠΑΝΑΡΑ, Πρόεδρος
K. PANARA, President of the Board

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**ΕΘΝΙΚΟ ΚΕΝΤΡΟ ΑΞΙΟΛΟΓΗΣΗΣ
ΤΗΣ ΠΟΙΟΤΗΤΑΣ & ΤΕΧΝΟΛΟΓΙΑΣ
ΣΤΗΝ ΥΓΕΙΑ Α.Ε.**

NATIONAL EVALUATION CENTER
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**ΠΑΡΑΡΤΗΜΑ ΤΟΥ ΥΠ. ΑΡΙΘΜ. 305081023 ΠΙΣΤΟΠΟΙΗΤΙΚΟΥ /
ANNEX I Nr. 305081023 CERTIFICATE.**


ΚΑΤΗΓΟΡΙΑ / CLASS Ia

	ΙΑΤΡΟΤΕΧΝΟΛΟΓΙΚΟ ΠΡΟΪΟΝ / MEDICAL DEVICE	ΤΥΠΟΣ / TRADE NAME
1.	ΡΙΝΙΚΑ ΕΠΙΘΕΜΑΤΑ/ PVA NASAL DRESSINGS	SIDA-CEL ENT
2.	ΧΕΙΡΟΥΡΓΙΚΕΣ ΠΟΔΙΕΣ / SURGICAL GOWNS	SIDAPHARM STERILE SURGICAL GOWNS, SIDAPHARM STERILE SURGICAL GOWNS WITH TOWELS
3.	ΟΦΘΑΛΜΟΛΟΓΙΚΑ ΠΕΔΙΑ / OPHTHALMIC DRAPES	SIDAPHARM STERILE OPHTHALMIC DRAPES
4.	ΟΦΘΑΛΜΙΚΑ ΤΡΙΓΩΝΑΚΙΑ PVA / PVA EYE SPEARS	SIDA-SPEARS PVA EYE SPEARS
5.	ΧΕΙΡΟΥΡΓΙΚΑ ΠΕΔΙΑ / SURGICAL DRAPES	SURGICAL DRAPE, MAYO SURGICAL COVER, SURGICAL DRAPE C-ARM, MICROSCOPE DRAPE, ANGIOGRAPHY DRAPE, ARTHROSCOPY DRAPE, C- SECTION DRAPE, FEMORAL & RADIAL ANGIOGRAPHY DRAPE

ΚΑΤΗΓΟΡΙΑ / CLASS IIa

	ΙΑΤΡΟΤΕΧΝΟΛΟΓΙΚΟ ΠΡΟΪΟΝ / MEDICAL DEVICE	ΤΥΠΟΣ / TRADE NAME
6.	ΑΠΟΣΤΕΙΡΩΜΕΝΑ ΟΦΘΑΛΜΙΚΑ ΜΑΧΑΙΡΙΔΙΑ/ STERILE OPHTHALMIC MICRO SURGICAL KNIVES	SIDAPHARM
7.	ΔΙΑΛΥΤΗ ΑΙΜΟΣΤΑΤΙΚΗ ΓΑΖΑ/ SOLUBLE HEMOSTATIC GAUZE	SIDA-CEL
8.	ΟΦΘΑΛΜΟΛΟΓΙΚΕΣ ΚΑΝΟΥΛΕΣ / OPHTHALMIC CANNULAS	SIDAPHARM OPHTHALMIC MICROSURGICAL CANNULAS


Σ. ΠΟΡΑΒΟΣ, Διευθύνων Σύμβουλος
S. PORAVOS, Managing Director


Κ. ΠΑΝΑΡΑ, Πρόεδρος
K. PANARA, President of the Board



**ΕΘΝΙΚΟ ΚΕΝΤΡΟ ΑΞΙΟΛΟΓΗΣΗΣ
ΤΗΣ ΠΟΙΟΤΗΤΑΣ & ΤΕΧΝΟΛΟΓΙΑΣ
ΣΤΗΝ ΥΓΕΙΑ Α.Ε.**

NATIONAL EVALUATION CENTER
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**ΠΑΡΑΡΤΗΜΑ ΤΟΥ ΥΠ. ΑΡΙΘΜ. 305081023 ΠΙΣΤΟΠΟΙΗΤΙΚΟΥ /
ANNEX I Nr. 305081023 CERTIFICATE.**

ΚΑΤΗΓΟΡΙΑ / CLASS IIb

	ΙΑΤΡΟΤΕΧΝΟΛΟΓΙΚΟ ΠΡΟΪΟΝ / MEDICAL DEVICE	ΤΥΠΟΣ / TRADE NAME
9.	ΑΠΟΣΤΕΙΡΩΜΕΝΑ ΙΣΟΤΟΝΑ ΑΛΑΤΟΥΧΑ ΔΙΑΛΥΜΑΤΑ ΕΚΠΛΥΣΗΣ / STERILE BALANCED SALT SOLUTIONS	SIDAPHARM BSS
10.	ΕΝΔΟΦΑΚΟΙ / INTRAOCULAR LENSES: - ΥΔΡΟΦΟΒΟΙ ΕΝΔΟΦΑΚΟΙ / HYDROPHOBIC INTRAOCULAR LENSES - ΥΔΡΟΦΙΛΟΙ ΕΝΔΟΦΑΚΟΙ / HYDROPHILIC INTRAOCULAR LENSES	-SIDA-LENS / HYDROPHOBIC ONE PIECE ACRYLIC FOLDABLE INTRAOCULAR LENSES -ORIZON / PRELOADED HYDROPHOBIC ONE PIECE ACRYLIC FOLDABLE INTRAOCULAR LENSES -SIDA-LENS / HYDROPHILIC ONE PIECE ACRYLIC FOLDABLE INTRAOCULAR LENSES
11.	ΟΦΘΑΛΜΟΛΟΓΙΚΑ ΔΙΑΛΥΜΑΤΑ/ OPHTHALMIC SOLUTIONS: - ΟΦΘΑΛΜΟΛΟΓΙΚΟ ΔΙΑΛΥΜΑ ΚΥΑΝΟΥΝ ΤΟΥ ΤΡΥΠΑΝΙΟΥ / TRYPAN BLUE OPHTHALMIC SOLUTION - ΟΦΘΑΛΜΟΛΟΓΙΚΟ ΔΙΑΛΥΜΑ / ΥΔΡΟΞΥΠΡΟΠΥΛΟΜΕΘΥΛΟΚΥΤΤΑΡΙΝΗΣ / HPMC OPHTHALMIC SOLUTION	-SIDA-BLUE, SIDA-BLUE PFS -SIDA-HPMC 2%

Σ. ΠΟΡΑΒΟΣ, Διευθύνων Σύμβουλος
S. PORAVOS, Managing Director

Κ. ΠΑΝΑΡΑ, Πρόεδρος
K. PANARA, President of the Board



ΟΡΟΙ & ΠΡΟΫΠΟΘΕΣΕΙΣ / TERMS & CONDITIONS

1. Για αποστειρωμένα προϊόντα κατηγορίας I, η πιστοποίηση αφορά μόνο τα θέματα επίτευξης και διατήρησης της αποστείρωσης.
For class I sterile products, the certificate covers only the aspects of manufacture concerned with securing and maintaining sterile conditions.
2. Για προϊόντα κατηγορίας I με λειτουργία μέτρησης, η πιστοποίηση αφορά μόνο τα θέματα συμμόρφωσης των προϊόντων προς τις μετρολογικές απαιτήσεις. /
For Class I devices with a measuring function the certificate covers only the aspects of manufacture concerned with the conformity of the products with metrological requirements.
3. Για προϊόντα κατηγορίας III, είναι απαραίτητο ένα συμπληρωματικό πιστοποιητικό Εξέτασης Σχεδιασμού σύμφωνα με τις απαιτήσεις της Οδηγίας 93/42/ΕΟΚ, Παράρτημα II (σημείο 4).
For class III products an additional Design Examination certificate is required according to the requirements of Annex II 93/42/EEC (section 4).
4. Το πιστοποιητικό ισχύει μόνο για τα προϊόντα και τις εγκαταστάσεις που αναφέρονται.
The certificate is valid only for the products and the facilities mentioned.
5. Θα πραγματοποιούνται περιοδικές επιθεωρήσεις επιτήρησης όπως αναφέρεται στην Οδηγία 93/42/ΕΟΚ, με σκοπό να επαληθεύεται ότι ο κατασκευαστής διατηρεί και εφαρμόζει το σύστημα ποιότητας.
Periodical surveillance as referred in 93/42/EEC will be held in order to verify that the manufacturer maintains and applies the quality system.
6. Όταν τηρούνται τα ανωτέρω, ο κατασκευαστής μπορεί να συντάσσει δήλωση συμμόρφωσης ΕΚ και να επιθέσει τη σήμανση CE 0653 στα καλυπτόμενα προϊόντα.
When meeting with the terms and conditions above, the manufacturer may draw up an EC declaration of conformity and legally affix the CE 0653 mark.



Health Technology Certification



QUALITY MANAGEMENT SYSTEM CERTIFICATE

This is to certify that
the quality management system of

SIDAPHARM P.C.

Headquarters: 21, Stageiriti & 24, Em. Fili str. Thessaloniki,
GR-54352, Greece

Branch: 6, Laertou str., Pylaia, Thessaloniki,
GR-55535, Greece

has been assessed by HTCert and found to comply with
EN ISO 9001:2015

Scope of certificate:

- Production, marketing and distribution of surgical and ophthalmic products.
- Distribution of personal protective equipment.

Certificate No:	1828C01210601
Original Approval:	09/06/2021
References:	W001 1828 05
Issue Date:	09/06/2021
Valid until:	08/06/2024

For and on behalf of HTCert

GEORGE PAPPOUS
Managing Director



FILIPPOS KOTTIS
Certification Director

Digitally signed by Pereteatco Alina
Date: 2021.10.08 09:52:38 EEST
Reason: MoldSign Signature
Location: Moldova





Health Technology Certification



QUALITY MANAGEMENT SYSTEM CERTIFICATE

This is to certify that
the quality management system of

SIDAPHARM P.C.

Headquarters: 21, Stageiriti & 24, Em. Fili str. Thessaloniki,
GR-54352, Greece

Branch: 6, Laertou str., Pylaia, Thessaloniki,
GR-55535, Greece

has been assessed by HTCert and found to comply with

EN ISO 13485:2016

Scope of certificate:

Production, marketing and distribution of surgical and ophthalmic products.

Certificate No:	1828C02210601
Original Approval:	09/06/2021
References:	W001 1828 05
Issue Date:	09/06/2021
Valid until:	08/06/2024

For and on behalf of HTCert

GEORGE PAPPOUS
Managing Director



FILIPPOS KOTTIS
Certification Director

Digitally signed by Pereteatco Alina
Date: 2021.10.08 09:54:48 EEST
Reason: MoldSign Signature
Location: Moldova





SIDAPHARM[®]

Ophthalmic & Medical Disposable Products

Ophthalmic Catalogue

Digitally signed by Pereteatco Alma
Date: 2021.10.07 23:37:14 EEST



Who we are

Sidapharm was founded in 2000 and is a CE-certified manufacturer of a vast range of ophthalmic products such as intraocular lenses, knives and cannulas, viscoelastics, BSS, cataract kits and ophthalmic instruments. Based in Thessaloniki, Greece, a city which connects Europe with Asia, Middle East and Africa, the company managed to take advantage of its location, expand its network and build strong collaborations through these continents.

Nowadays, Sidapharm has presence in more than 50 countries, mostly through very dynamic and reliable distributors. Our focus is on investing in long-lasting partnerships and on that ground we assist our distributors in every possible way, to become competitive and win every day bigger market shares.



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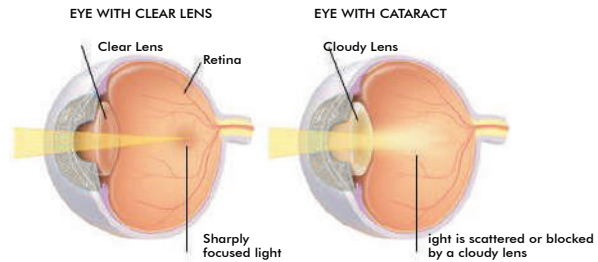
13

Intraocular Lenses **SIDA-LENS™**

Embracing the constant need for development and improvement Sidapharm's IOLs result in an innovative and high-quality product. Thoroughly inspected for their resolution, diopter, surface quality and dimensions they provide excellent perception.

After **SIDA-LENS™** implantation recipients enjoy optimal optical outcome.

The IOLs are accompanied by an injector and can be smoothly implanted through a small incision



Hydrophobic IOLs

CAST MOLDING TECHNOLOGY

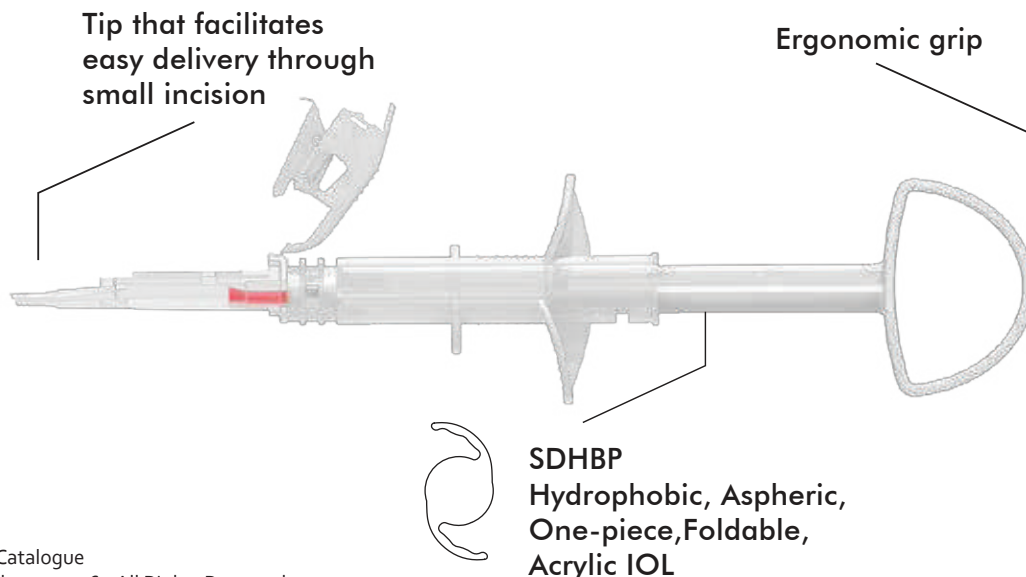
Superb quality of raw materials using pre-molded blanks

Biocompatible hydrophobic acrylic material with UV absorption

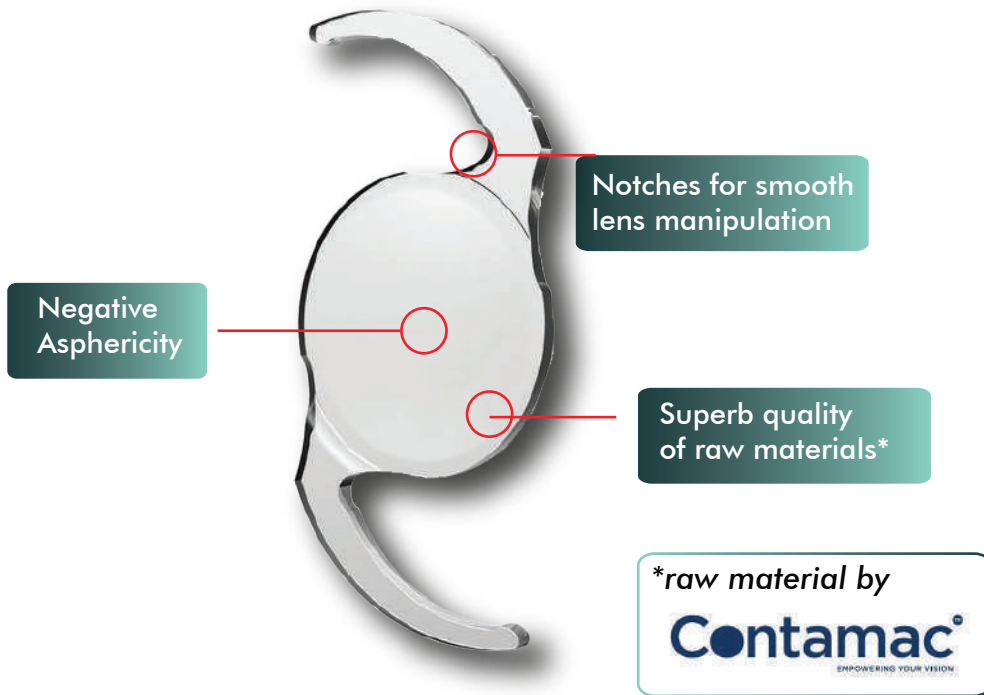
With **Biconvex surfaces** which minimize effects of tilt, decentration and aberration and with a 360° square-edge profile for reduced PCO rates

PREMIUM PRECISION

HYDROPHOBIC PRELOADED SYSTEM SDHBP

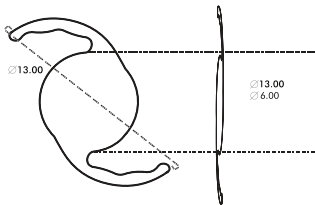


HYDROPHOBIC IOL SDHB6130



SDHB6130

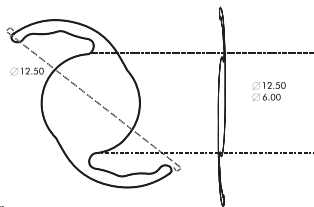
Aspheric,
360° Square Edge



Optic Design: Biconvex
Optic Size: 6.00
Overall Length: 13.00
Haptic Angle: 0°
Refractive Index 1.56
A-constant: 118.5
AC depth:5.00

SDHBY

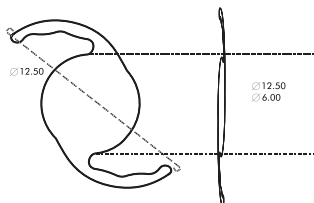
Aspheric,
360° Square Edge
Yellow, Blue Light Filtering



Optic Design: Biconvex
Optic Size: 6.00
Overall Length: 12.50
Haptic Angle: 0°
Refractive Index 1.49
A-constant: 118.0
AC depth:5.00

SDHB

Aspheric,
360° Square Edge



Optic Design: Biconvex
Optic Size: 6.00
Overall Length: 12.50
Haptic Angle: 0°
Refractive Index 1.49
A-constant: 118.0
AC depth:5.00

Hydrophilic IOLs

Exceptional biocompatibility and UV absorption

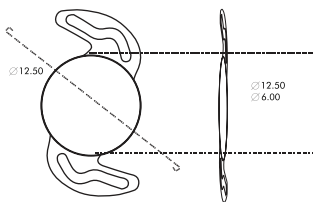
High Resolution, Diopter Accuracy Preciseness

Easy lens manipulation

Controlled surgical handling

SDA

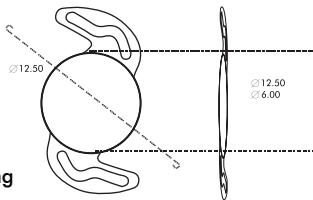
Aspheric,
360° Square Edge



Optic Design: Biconvex
Optic Size: 6.00
Overall Length: 12.50
Haptic Angle: 0°
Refractive Index: 1.46
A-constant: 118.0
AC depth: 5.00

SDYA

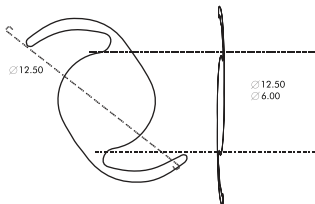
Aspheric,
360° Square Edge,
Yellow, Blue Light Filtering



Optic Design: Biconvex
Optic Size: 6.00
Overall Length: 12.50
Haptic Angle: 0°
Refractive Index: 1.46
A-constant: 118.0
AC depth: 5.00

SDAC

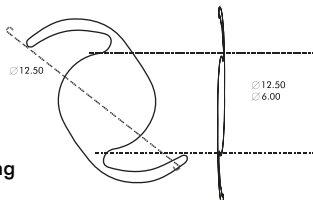
Aspheric,
360° Square Edge



Optic Design: Biconvex
Optic Size: 6.00
Overall Length: 12.50
Haptic Angle: 5°
Refractive Index: 1.46
A-constant: 118.0
AC depth: 5.00

SDACY

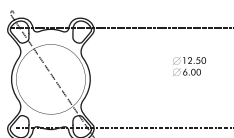
Aspheric,
360° Square Edge
Yellow, Blue Light Filtering



Optic Design: Biconvex
Optic Size: 6.00
Overall Length: 12.50
Haptic Angle: 5°
Refractive Index: 1.46
A-constant: 118.0
AC depth: 5.00

SDA4

Aspheric,
360° Square Edge



Optic Design: Biconvex
Optic Size: 6.00
Overall Length: 11.00
Haptic Angle: 0°
Refractive Index: 1.46
A-constant: 118.0
AC depth: 5.00

PMMA, One-Piece

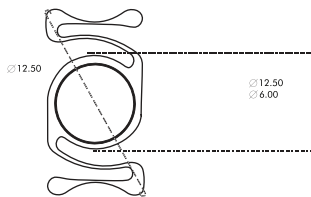
Clinical quality PMMA with **UV absorber**

YAG laser compatible

ANTERIOR CHAMBER

SDANT

4 points of fixation

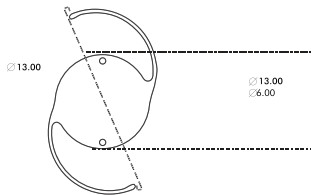


Optic Design: Biconvex
Optic Size: 6.00
Overall Length: 12.50
Haptic Design: S Loop
Refractive Index 1.52
A-constant: 115.3
AC depth: 2.95

POSTERIOR CHAMBER

SDHS

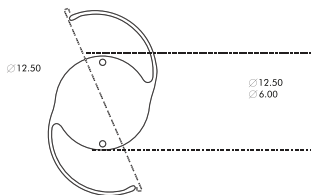
2 Dialing holes



Optic Design: Biconvex
Optic Size: 6.00
Overall Length: 13.00
Haptic Design: C Loop
Refractive Index 1.52
A-constant: 118.2
AC depth: 4.80

SDALP

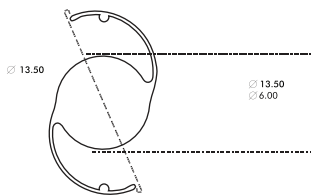
2 Dialing holes



Optic Design: Biconvex
Optic Size: 6.00
Overall Length: 12.50
Haptic Design: C Loop
Refractive Index 1.52
A-constant: 118.4
AC depth: 5.00

SDSFP

2 Eyelets



Optic Design: Biconvex
Optic Size: 6.50
Overall Length: 13.50
Haptic Design: C Loop
Refractive Index 1.52
A-constant: 118.2
AC depth: 4.80

Ophthalmic Microsurgical Knives

Chemically polishing technology

Minimized micro-roughness

Cleanability of surfaces

Low contamination levels

Effect of chemical polishing on surface finish



Surface Before Electropolishing



Surface After Electropolishing

Check our Superiority!
(microscope photos)



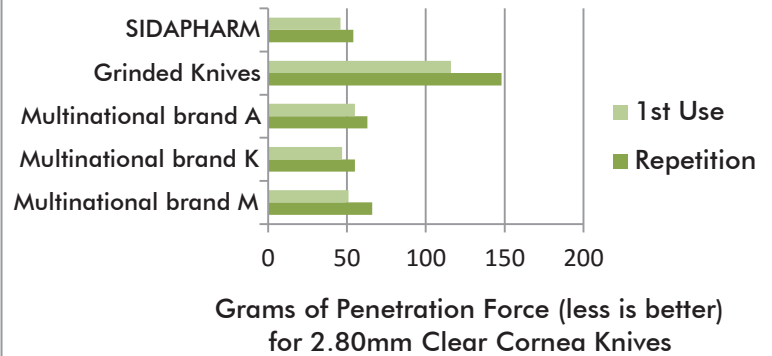
**SIDAPHARM®
Knives**

- ✓ Even Edges
- ✓ Smooth Surface



- Other
Grinded Knives**
- ✗ Uneven Edges
 - ✗ Scratched Surface

Sharpness Comparison



Precision
Diamond
like sharpness
Exact Dimensions

Quality
Matt
anti-glare
finish

Performance
Incisions with
accuracy and
complete control

Minimum wound for rapid healing
Perfect visibility of the blade within the eye chamber



Ophthalmic Microsurgical Knives

All-procedures microsurgical knives

Our knives allow enhanced control and precision, deliver great sharpness and quality, while maintaining the cost low.

Stab Knives



Ref. No.	Description
62000	15°
62021	22.5°
62001	30°
62002	45°

Crescent Knives



Ref. No.	Description
62003	Angled
62003-1	Straight

MVR Knives



Ref. No.	Description
62004	19G (1.5mm) Straight
62009	19G (1.5mm) Angled
62005	20G (1.2mm) Straight
62010	20G (1.2mm) Angled
62007	23G (0.9mm) Straight
62012	23G (0.9mm) Angled

Slit Knives



Ref. No.	Description
62016	2.20mm Angled
62017	2.40mm Angled
62052	2.60mm Angled
62018-1	2.75mm Angled
62018*	2.80mm Angled
62019*	3.00mm Angled
62020*	3.20mm Angled

Implant Knives (Rounded Tip)



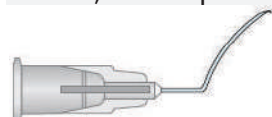
Ref. No.	Description
62015	5.10mm Angled
62027	5.20mm Angled

Ophthalmic Cannulas

Steel and Plastic of the highest quality
Guaranteed hygiene
Constant Development & Improvement

Cystotomes

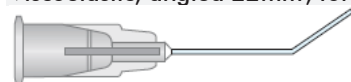
Formed, 16mm tip



Ref. No.	Description
77005	23G
77006	25G
77007	27G
77008	30G

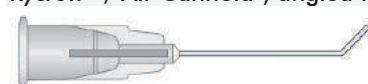
Anterior Chamber

Viscoelastic, angled 22mm, formed



77104	25G
77082	27G

Rycroft / Air Cannula , angled tip



77044	23G, 4mm
77001	25G, 8mm
77003 - 1	27G, 4mm
77056	27G, 8mm
77003	27G, 10mm
77046	30G, 4mm
77004	30G, 6mm

Hydrodissectors

Angled, flat tip



77062	23G, 8mm tip
77010	25G, 8mm tip
77012	27G, 8mm tip
77013	30G, 8mm tip

Curved, flat tip



77014	27G, Horizontal tip
77063	27G, Vertical tip

J-shaped, vertical flat tip



77067	25G
77068	27G

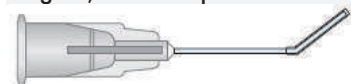
Capsule Polishers

Posterior, angled top port



77073	21G, 9mm tip
77074	23G, 9mm tip






Angled, silicon tip



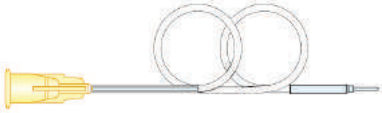
77070	23G, 7mm tip
77072	23G, 9mm tip
77071	27G, 7mm tip

Ophthalmic Cannulas

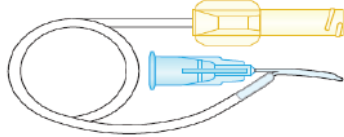
Anesthesia

	Ref. No.	Description
Retrobulbar, straight Atkinson tip		
	77026	23G, 38mm tip
	77027	25G, 38mm tip
	77028	27G, 38mm tip
Retrobulbar, curved Atkinson tip		
	77033	25G, 38mm tip
Retrobulbar, straight sharp tip		
	77034	25G, 25mm tip
	77035	25G, 38mm tip
	77036	30G, 12.5mm tip
Subtenon		
	77032	19G, 22mm tip
Peribulbar, straight Atkinson tip		
	77029	23G, 22mm tip
	77037	23G, 32mm tip
	77030	25G, 22mm tip
	77038	25G, 32mm tip

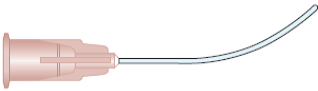
A/C Maintainers

	77015	19G, Screw tip
	77088	19G, Smooth tip
	77016	20G, Screw tip
	77041	20G, Smooth tip
	77089	21G, Smooth tip
	77040	23G, Screw tip

Simcoe

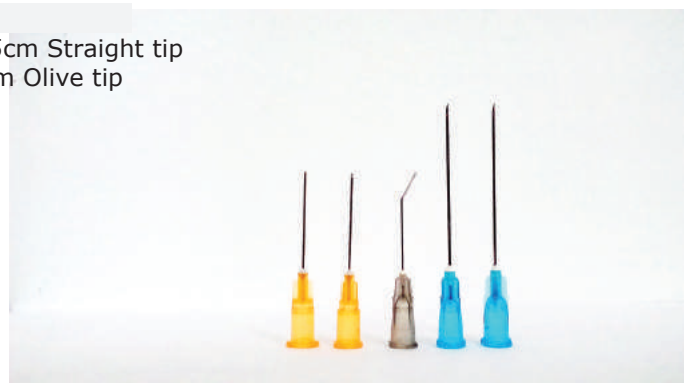
	77022	20G
	77025	23G

Lacrimal

Lacrimal, 28mm		
	77021	26G

Intubation Set

	77083	23G, 17.5cm Straight tip
	77084	23G, 11cm Olive tip



Ophthalmic Viscoelastics (OVDs)

SIDA-VISC™ Sodium Hyaluronate Ophthalmic Solutions

Provides the protection and control needed during the ophthalmic operations of :

- > Cataract extraction
- > IOL implementation
- > Glaucoma filtering surgery
- > Corneal transplantation surgery

Product features:

- > High viscosity for space creation during operations
- > Very easy injection and removal from the eye
- > Latex-free
- > It provides excellent endothelial protection
- > Ideal for cartridge lubrication during IOL implantation

Available in 1 ml pre-filled syringe with the following concentrations (cohesive/dispersible)

10mg/ml 14mg/ml 15 mg/ml 18 mg/ml



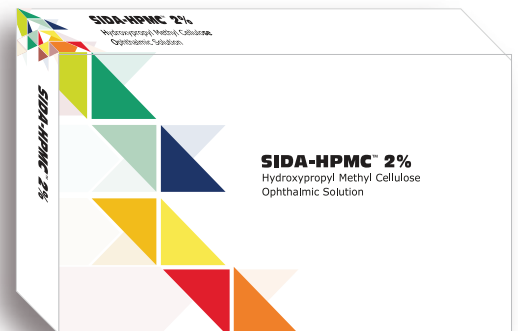
SIDA-HPMC™ 2% Hydroxypropyl Methyl Cellulose (HPMC) Ophthalmic solution

Offering an ophthalmic viscosurgical device that has low viscosity properties, is ideal for coating and protecting the eye during anterior segment surgical procedures.

SIDA-HPMC 2% exhibits moderate viscoelasticity characteristics, with retentive but also excellent tissue coating abilities. Offers good space maintenance and excellent tissue protection throughout the ophthalmic procedure

KEY Product features

- > Low molecular weight and low surface tension
- > High concentration of HPMC
- > Non-antigenic (allergic)
- > Non-pyrogenic
- > Completely transparent
- > Sterile pre-filled syringe supplied with a cannula
- > Available in 2 ml luer-lock glass syringe and 3ml plastic syringe
- > Preservative-free



Preservative-free
Ambient storage

Ophthalmic Solutions

SIDA-BLUE™

Trypan Blue Ophthalmic Solution 0.06 v/w

Excellent visualization of the capsulorhexis in eyes with mature cataract or small pupils
Clear outline of the capsulorhexis rim during the entire surgery.
Capsule staining is quick, easy and safe to perform.
Creates excellent staining contrast for anterior and posterior capsulorhexis
Reduces surgical time.



Indicated for:

- > For Cataract surgery with poor red reflex
- > Phacoemulsification
- > Small incision cataract surgery
- > Extra capsular cataract surgery
- > Incomplete capsulorhexis
- > Anterior/posterior capsulotomy
- > Any high risk cataract case
- > Trauma Cases
- > Teaching trainee surgeons

Available in :
1 ml vial



Prefilled syringe
Ready to use syringe. NO mixing required.
Ergonomic grip for better control of the injection



BSS Balanced Salt Solution

BSS is a sterile physiological solution for use in irrigating ocular tissues of the eye.
It hydrates and protects tissues and cells during any ophthalmic surgery.

Indicated for:

- > Refractive surgery
- > Phacoemulsification
- > Vitrectomy
- > Corneal irrigation

Available in a two way volumetric 500ml plastic bottle
with retractable, attached, hanging loop at the base.

Now also available in 250ml & 500ml GLASS BOTTLE



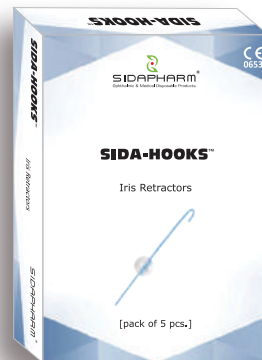
Miscellaneous Disposables

SIDA-HOOKS™

Iris Retractors

Flexible hooks used to increase pupillary diameter during surgery. The attached silicon stopper allows better grip and easy adjustment of pupil size.

Provided in a sterile pack of 5 pieces



SIDA- RINGS™

CTR / Capsular tension Rings

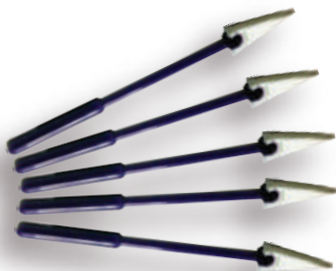
Rings in order to safely ensure stability and support centration.

Available in variations in sizes



SIDA-SPEARS™

Eyespears



A soft, asorbing tool to drain excessive fluids.

Provided in a sterile pack of 5 pieces, available in PVA or Cellulose material.

EYE SHIELDS



For preventive use after surgery. Made from light and strong plastic, protects the eye and keeps it properly ventilated.

Non-sterile

Cataract Packs

Specially designed for cataract eye operations.
Ideal as one-stop supply solution.
Great quality for great price.

Basic Cataract Pack

Designed to be user friendly, convenient and efficient in order to meet any special needs of the doctor and the surgical team

- 1 x Table Cover (140cm x 150cm)
- 1 x Ophthalmic Drape with pouch (100cm x 120cm)
- 1 x Surgical Drape (100cm x 160cm)
- 1x 1ml syringe 26g
- 2x 3ml syringe
- 2x 5ml syringe
- 1x 10ml syringe
- 10x Gauze swab 7.5 x 7.5
- 1x Eyepad
- 2x Gowns with towels (Large)
- 1x 60 ml plastic bowl
- 5x Eye spears

Custom Cataract Pack

Build your own customized surgery pack choosing among the full range of cataract and ophthalmic disposables product line.

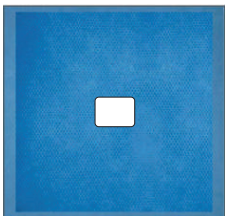
Contact SIDAPHARM'S team to prepare a high-quality and cost effective pack.



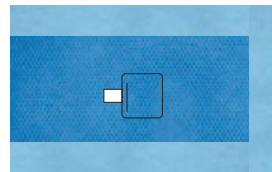
Surgical Apparel

After years of constant research and cooperation with doctors our complete line of surgical apparel is here to cover your needs. Individually sterile packaging optimizes time and resources .

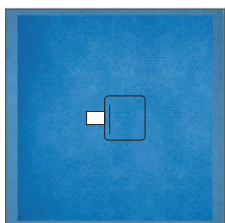
Bigger variety is available in sizes and features(i.e. adhesive tape).
Custom solutions !



20028
Ophthalmic Drape
55g 2ply
Spunlaced non-woven
50cm x 60 cm



20028
Ophthalmic Drape
55g 2ply
With pouch and incision film
50cm x 60 cm



20014
Ophthalmic Drape
40g SMS
With pouch and incision film
100cm x 120 cm



25001
Surgical Gown
50gsm SMS non-woven
Fluid repellent
Provides unrestricted movement



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Ophthalmic & Medical Disposable Products

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