Italia

CERTIFICATO

Nr. 50 100 11497 Rev.005

SI ATTESTA CHE / *THIS IS TO CERTIFY THAT*

IL SISTEMA DI GESTIONE PER LA QUALITÀ DI
THE QUALITY MANAGEMENT SYSTEM OF

LIOFILCHEM S.r.l.

SEDE LEGALE:
REGISTERED OFFICE:

VIA SCOZIA - ZONA INDUSTRIALE
IT - 64026 ROSETO DEGLI ABRUZZI (TE)

SEDI OPERATIVE: **VEDI ALLEGATO 1** / *OPERATIONAL SITES:* ***SEE ANNEX 1***

È CONFORME AI REQUISITI DELLA NORMA
HAS BEEN FOUND TO COMPLY WITH THE REQUIREMENTS OF

UNI EN ISO 9001:2015

QUESTO CERTIFICATO È VALIDO PER IL SEGUENTE CAMPO DI APPLICAZIONE
THIS CERTIFICATE IS VALID FOR THE FOLLOWING SCOPE OF APPLICATION

Progettazione e sviluppo, produzione e vendita di dispositivi medico diagnostici in-vitro: terreni di coltura per microbiologia, sistemi di identificazione e antibiogramma, strip per determinazione della Minima Concentrazione Inibente, dischetti antibiotici, kit per la determinazione di plasmaproteine. Distribuzione di altri dispositivi medico diagnostici in-vitro (IAF 12, 29)

Design and development, production and sales of in-vitro diagnostic medical devices: culture media for microbiology, identification and susceptibility testing systems, Minimum Inhibitory Concentration test strips, antibiotic discs, kits for plasma protein determination. Distribution of other in-vitro diagnostic medical devices (IAF 12, 29)

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 049A

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

Per l'Organismo di Certificazione
For the Certification Body
TÜV Italia S.r.l.

Francesco Scarlata
Direttore Divisione Business Assurance
Business Assurance Division Manager

Validità / *Validity*

Dal / From: **2022-02-11**

Al / To: **2025-02-10**

Data emissione / *Issuing Date*

2022-01-26

PRIMA CERTIFICAZIONE / *FIRST CERTIFICATION:* 2012-09-25

DATA DI SCADENZA DELL'ULTIMO CICLO DI CERTIFICAZIONE: 2022-02-10
EXPIRATION DATE OF THE LAST CERTIFICATION CYCLE: *2022-02-10*

"LA VALIDITÀ DEL PRESENTE CERTIFICATO È SUBORDINATA A SORVEGLIANZA PERIODICA A 12 MESI E AL RIESAME COMPLETO DEL SISTEMA DI GESTIONE AZIENDALE CON PERIODICITÀ TRIENNALE"
"THE VALIDITY OF THE PRESENT CERTIFICATE DEPENDS ON THE ANNUAL SURVEILLANCE EVERY 12 MONTHS AND ON THE COMPLETE REVIEW OF COMPANY'S MANAGEMENT SYSTEM AFTER THREE-YEARS"

Italia

ALLEGATO 1 AL CERTIFICATO NR **50 100 11497 Rev.005**
ANNEX 1 *TO CERTIFICATE NO* ***50 100 11497 Rev.005***
pagina 1 di 1 / *page 1 of 1*

IL CERTIFICATO NR 50 100 11497 Rev.005 COPRE ANCHE LE SEGUENTI SEDI OPERATIVE:
THE CERTIFICATE N *50 100 11497 Rev.005 COVERS ALSO THE FOLLOWING OFFICES:*

LIOFILCHEM S.r.l.

VIA SCOZIA - ZONA INDUSTRIALE IT - 64026 ROSETO DEGLI ABRUZZI (TE)

Progettazione e sviluppo, produzione e commercializzazione di dispositivi medico diagnostici in-vitro: terreni di coltura per batteriologia, sistemi di identificazione e antibiogramma, kit per la determinazione di plasmaproteine

Production and sales of in-vitro diagnostic medical devices: dehydrated and ready-to-use culture media for microbiology

VIA URUGUAY IT - 64026 ROSETO DEGLI ABRUZZI (TE)

Progettazione e sviluppo, produzione e vendita di dispositivi medico diagnostici in-vitro: terreni di coltura pronti per microbiologia, reagenti e supplementi, sistemi di identificazione e antibiogramma, strip per determinazione della Minima Concentrazione Inibente, dischetti antibiotici, kit per la determinazione di plasmaproteine. Distribuzione di altri dispositivi medico diagnostici in-vitro. Progettazione e sviluppo e commercializzazione di terreni di coltura disidratati per microbiologia

Design and development, production and sales of in-vitro: diagnostic medical devices: ready-to-use culture media for microbiology, reagents and supplements, microbial identification and antimicrobial susceptibility testing systems, Minimum Inhibitory Concentration test strips, antibiotic discs, plasma protein determination kits. Distribution of other in-vitro diagnostic medical devices. Design and development and distribution of dehydrated culture media for microbiology

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 049A

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

Per l'Organismo di Certificazione
For the Certification Body
TÜV Italia S.r.l.

Francesco Scarlata
Direttore Divisione Business Assurance
Business Assurance Division Manager

Validità /*Validity*

Dal / From: **2022-02-11**

Al / To: **2025-02-10**

Data emissione /
Issuing Date

2022-01-26

PRIMA CERTIFICAZIONE / *FIRST CERTIFICATION:* 2012-09-25

DATA DI SCADENZA DELL'ULTIMO CICLO DI CERTIFICAZIONE: 2022-02-10
EXPIRATION DATE OF THE LAST CERTIFICATION CYCLE: *2022-02-10*

"LA VALIDITÀ DEL PRESENTE CERTIFICATO È SUBORDINATA A SORVEGLIANZA PERIODICA A 12 MESI E AL RIESAME COMPLETO DEL SISTEMA DI GESTIONE AZIENDALE CON PERIODICITÀ TRIENNALE"
"THE VALIDITY OF THE PRESENT CERTIFICATE DEPENDS ON THE ANNUAL SURVEILLANCE EVERY 12 MONTHS AND ON THE COMPLETE REVIEW OF COMPANY'S MANAGEMENT SYSTEM AFTER THREE-YEARS"

Sabouraud Dextrose Agar + Neutralizing (Irradiated)

Medium for detection of yeasts and moulds with inactivation of disinfectants.

TYPICAL FORMULA*	(g/l)
Pancreatic Digest of Casein	5.0
Peptic Digest of Animal Tissue	5.0
Dextrose	40.0
Agar	15.0
Histidine	1.0
Lecithin	0.7
Polysorbate 80	5.0
Sodium Thiosulfate	0.5
Final pH 5.6 ± 0.2	

*Formula may be adjusted and/or supplemented as required to meet performance specifications

DESCRIPTION

Sabouraud Dextrose Agar + Neutralizing is a solid culture medium used for the determination of total aerobic viable count of yeasts and moulds in procedures for environmental monitoring and other applications.

The composition of the base culture medium (SDA) complies with the recommendations of the harmonized USP/EP/JP method and EN ISO 11133. In addition, neutralizing agents are included in the medium to inactivate residual disinfectants allowing detection of microorganisms surviving after treatment of surface and material with antiseptics.

These gamma-irradiated, triple-bagged plates are particularly suitable for use in restricted areas like isolators and clean rooms.

PRINCIPLE

Pancreatic digest of casein and peptic digest of animal tissue provide amino acids, nitrogen, carbon, minerals, vitamins and other nutrients which support the growth of microorganism. Dextrose is an energy source. Agar is the solidifying agent. The high concentration of dextrose and the acidic pH of the medium permit selectivity of fungi. Histidine inactivates aldehydes. Lecithin neutralizes quaternary ammonium compounds. Polysorbate 80 (Tween 80) is effective against phenolic compounds and mercurial derivates. Sodium thiosulfate neutralizes halogen compounds.

TECHNIQUE

Take a swab sample for irregular surfaces or use the sampling template 10x10 (ref. 96762) to sample a well defined area of the test surface. Inoculate an agar plate by streaking the swab over the agar surface. Gloves can be sampled (prior to removing or replacement) by touching all fingers and thumbs onto the agar surface.

Incubate inoculated plates aerobically at 30-35°C for 24-48 hours for determination of the total aerobic bacterial count, while for determination of the total aerobic bacterial count, plates are incubated at 20-25°C for 5-7 days. Individual incubation conditions can be chosen and should be validated at the application site.

INTERPRETATION OF RESULTS

Observe for the formation of fungal colonies exhibiting typical microscopic and colonial morphology. Record the number of CFU per plate. Colonies should be further isolated and identified with appropriate procedures.

STORAGE

Store at 10-25°C away from light. Do not use the product beyond its expiry date on the label or if product shows any evidence of contamination or any sign of deterioration.

WARNING AND PRECAUTIONS

For professional use only. Operators must be trained and have certain experience in the laboratory methods. Please read the instructions carefully before using this product. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this document.

Consult the Safety Data Sheet (SDS) for information regarding hazards and safe handling practices.

DISPOSAL OF WASTE

Disposal of waste must be carried out according to the national and local regulations in force.

REFERENCES

1. EN ISO 11133:2014+Amd1:2018+Amd2:2020. Microbiology of food, animal feed and water − Preparation, production, storage and performance testing of culture media.
2. USP 41 NF 36 (2018): <61> Microbiological Examination of Non-Sterile Products: Microbial Enumeration Tests; <1116> Microbiological Control and Monitoring of Aseptic Processing Environments.
3. EP 9.0 (2016): 2.6.12. Microbial examination of non-sterile products (total viable aerobic count).
4. JP 16th edition (2011): 4.05 Microbial Limit Test.
5. EU GMP Medicinal Products for Human and Veterinary use (2008): Annex1 Manufacture of Sterile Medicinal Products.
6. FDA Guidance for Industry (2004): Sterile Drug Products Produced by Aseptic Processing - Current Good Manufacturing Practice.
7. Swanson, K.J., F.F. Busta, E.H. Peterson, and M.G. Johnson (1992). Colony Count Methods, p. 75-95.

LIOFILCHEM® S.r.l.
Via Scozia, Zona Ind.le - 64026, Roseto degli Abruzzi (TE) - ITALY
Tel +39 0858930745 Fax +39 0858930330 www.liofilchem.com liofilchem@liofilchem.com

PRODUCT SPECIFICATIONS

NAME

Sabouraud Dextrose Agar + Neutralizing (irradiated)

STORAGE

10-25°C

pH OF THE MEDIUM

5.6 ± 0.2

USE

Sabouraud Dextrose Agar + Neutralizing is a medium used for cultivation of yeasts and moulds with inactivation of disinfectants

SHELFLIFE

6 months

QUALITY CONTROL

Appearance of Medium: Slightly opalescent, light amber

Expected Cultural Response

Inoculum: 50-100 CFU

Incubation: 30-35°C for 24 h (*C. albicans*) and 20-25°C for up to 3 days (all control strains)

Control strains		**Specification**
Candida albicans	WDCM 00054 (ATCC® 10231, NCPF 3179)	Good growth ($P_R \geq 0.7$)
Aspergillus brasiliensis	WDCM 00053 (ATCC® 16404, NCPF 2275)	
Saccharomyces cerevisiae	WDCM 00058 (ATCC® 9763, NCTC 10716)	

A productivity ratio (P_R) of 0.7 is equivalent to a recovery rate of 70%
Please refer to the actual batch related Certificate of Analysis (CoA)

PACKAGING

Ref. 10075S 90 mm Plate 20 (2 x 10) plates

TABLE OF SYMBOLS

LOT Batch code	Do not reuse	Manufacturer	Use by	Fragile, handle with care
REF Catalogue number	Temperature limitation	Contains sufficient for <n> tests	Caution, consult instructions for use	

LIOFILCHEM® S.r.l.
Via Scozia, Zona Ind.le - 64026, Roseto degli Abruzzi (TE) - ITALY
Tel +39 0858930745 Fax +39 0858930330 www.liofilchem.com liofilchem@liofilchem.com

STRIP CONTROL BAT E8/E7/E6/E5/E4/E3

ENGLISH

Biological indicators of dry heat or ethylene oxide sterilization processes containing *Bacillus atropheus* (ATCC 9372) spores inoculated on special filter paper strips

DESCRIPTION

USP (United States Pharmacopoeia), EP (European Pharmacopoeia) and DAB (Deutsches Arzneibuch) standards, recommend to use bioindicators during dry heat and ethylene oxide sterilization processes.
Biological indicators **STRIP CONTROL BAT E8/E7/E6/E5/E4/E3** are special filter paper strips, inoculated with *Bacillus atropheus* (ATCC 9372) spores in predefined concentrations and contained in a special envelope. These bioindicators are used for validation, re-validation and process monitoring of dry heat and ethylene oxide sterilizers.
Biological indicators **STRIP CONTROL BAT E8/E7/E6/E5/E4/E3** are produced under strictly controlled conditions in order to satisfy the requirements indicated in the USP current edition and in accordance with ISO 11138 and EN 866 standards.

PRINCIPLE

STRIP CONTROL BAT E8/E7/E6/E5/E4/E3 contain *Bacillus atropheus* (ATCC 9372) spores in predefinited concentrations: E8=1-5x10^8UFC/strip; E7=1-5x10^7CFU/strip; E6=1-5x10^6CFU/strip; E5=1-5x10^5CFU/strip; E4=1-5x10^4 CFU /strip; E3=1-5x10^3 CFU /strip.
Spores in the strips are completely killed off during dry heat or ethylene oxide sterilization process, if the process has been efficient. In this case the aspect of Steri-Test Medium (included in the package), inoculated with the strips and incubated for a suitable time will remain unchanged: violet/clear.
On the contrary, if the sterilization process has not been efficient, spores partially survive and Steri-Test Medium turns from violet/clear to yellow/turbid.

INTRUCTIONS FOR USE

- Take one or more strips from the kit leaving them inside their original envelope.
- Put envelopes with strips on the bottom, in the centre, inner sides and on the critical points of the sterilizer.
- For sterilizers with capacity up to 250 litres put two envelopes for each selected point of the sterilizer. For sterilizers with capacity higher than 250 litres put six or more envelopes in each selected point.
- Remove envelopes after sterilization/aeration cycle and open them aseptically with sterile scissors or by tearing the edges.
- Transfer aseptically each strip from its envelope to a Steri-Test Medium tube, included in the package.
- Incubate tubes containing strips at 30-35°C (86-95°F) for 7 days or for a shorter time validated by user.
- Incubate, at the same conditions of time and temperature, a strip contained in the envelope not submitted to the sterilization cycle, belonging to the same batch, as spore growth control (positive control).
- Examine tube medium's colour and interpret results as per **EVALUATION TABLE**: a change of medium's colour from violet/clear to yellow/turbid indicates a microbial growth and therefore an unsuccessful sterilization. On the contrary, the persistence of the medium's initial colour (violet/clear) indicates absence of microbial growth and therefore a successful sterilization.

EVALUATION

Bacillus atropheus (ATCC 9372) spores are killed off if the sterilization cycle has been efficient: in this case the medium's colour remains violet/clear even after incubation at 30-35 °C (86-95 °F) for the selected time.
If the sterilization cycle has not been efficient, spores partially survive and the tube's content turns yellow/turbid after incubation at 30-35 °C (86-95 °F) for the selected time.
The tube inoculated with the strip contained in the envelope, not submitted to the sterilization cycle and used as spore growth control, has to turn yellow/turbid after incubation. On the contrary, the test must to be repeated after having investigated causes of the negative result.

EVALUATION TABLE		
MEDIUM COLOUR	**SPORE**	**STERILIZATION**
Violet / Clear	Killed off	Successful
Yellow / Turbid	Vital	Unsuccessful

TREATMENT OF STERILTEST MEDIUM TEST TUBES AFTER USE

After use, sterilize the positive tubes (yellow/turbid) in autoclave at 121 °C for at least 30 minutes and eliminate them in accordance with the procedures of the laboratory.

STORAGE

Store the product at 2-8 °C: in these conditions it maintains its validity until the expiry date indicated on the label.

BIBLIOGRAPHY

1. United States Pharmacopoeia latest edition.
2. Deutsches Arzneibuch latest edition.
3. European Pharmacopoeia latest edition.
4. ISO 11138 and EN 866 latest edition.

PRESENTATION

PRODUCT	CODE	PACKAGING	Spores: CFU/strip	D_{EO} (600 ± 30 mg/L, 60% ± 10% RH, 54 ± 1 °C)	D_{DH} (160 ± 1 °C)
STRIP CONTROL BAT E8	91059	20 buste+20 provette di Steri-Test Medium	1-5x10^8	2,6-4,5 minutes	1,0-3,0 minutes
STRIP CONTROL BAT E7	91062	20 buste+20 provette di Steri-Test Medium	1-5x10^7	2,6-4,5 minutes	1,0-3,0 minutes
STRIP CONTROL BAT E6	91063	20 buste+20 provette di Steri-Test Medium	1-5x10^6	2,6-4,5 minutes	1,0-3,0 minutes
STRIP CONTROL BAT E5	91064	20 buste+20 provette di Steri-Test Medium	1-5x10^5	2,6-4,5 minutes	1,0-3,0 minutes
STRIP CONTROL BAT E4	91065	20 buste+20 provette di Steri-Test Medium	1-5x10^4	2,6-4,5 minutes	1,0-3,0 minutes
STRIP CONTROL BAT E3	91066	20 buste+20 provette di Steri-Test Medium	1-5x10^3	2,6-4,5 minutes	1,0-3,0 minutes

D value for ethylene oxide (D_{EO}) is calculated with the MPN and SC methods with 600±30 mg/L of ethylene oxide, at a temperature of 54±1°C, with 50-70% humidity.
D value for dry heat (D_{DH}) is calculated with MPN method at a temperature of 160±1°C.

TABLE OF SYMBOLS

Manufacturer	Contains sufficient for <n> tests	Temperature limitation
REF Catalogue number	Fragile, handle with care	Caution, consult accompanying documents
Use by	LOT Batch code	Do not reuse

LIOFILCHEM Bacteriology Products
Via Scozia Zona Ind.le - 64026 Roseto D.A. (TE) - Italy
Tel. +390858930745 Fax +390858930330 Website: *www.liofilchem.net* E-Mail: *liofilchem@liofilchem.net*

F12311
Rev.0 / 17.01.2005

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 029056 0067 Rev. 00

Manufacturer:

ALPRO MEDICAL GMBH
Mooswiesenstraße 9
78112 St. Georgen
GERMANY

Facility(ies):

ALPRO MEDICAL GMBH
Mooswiesenstraße 9, 78112 St. Georgen, GERMANY

Product Category(ies):

- **Cleaning and disinfection preparations for water-bearing lines of medical and dental treatment units**
- **Cleaning and disinfection preparations for aspiration and separation systems as well as spittoon bowls of medical and dental treatment units**
- **Disinfection preparations for surfaces of medical products**
- **Preparations for cleaning and disinfection of medical and dental instruments including rotary instruments and endoscopes**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 713140253

Valid from: 2019-01-18
Valid until: 2023-12-31

Date, 2019-01-18

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

DesNet +

CE 0123

Liquid concentrate free of aldehydes and phenols

with comprehensive microbicidal efficacy for the cleaning and disinfection of surfaces of medical devices.

Efficacy/Certification

- **bactericidal** incl. MRSA and suitable for hospitalism prophylaxis
- **fungicidal** (A. niger, C. albicans)
- **virucidal** according to EN 14476 all enveloped and non-enveloped viruses incl. polio
- **sporicidal** against C. difficile (EN 13704)

Contact times

- **General Hygiene and prophylaxis:**
  bactericidal, fungicidal and virucidal against enveloped viruses (s. efficacy)
  1,0 % – 60 min. / 2.0 % – 15 min.

- **Critical areas (e.g. operating room):**
  bactericidal, fungicidal and virucidal **(against enveloped and non-enveloped „blood-borne“ viruses)** (see efficacy)
  4.0 % – 60 min. / 5.0 % – 15 min.

Active ingredient basis

- Contemporary combination based on QAC, tensides and complexing agents

Delivery form

- **REF 3027** – 1 L
- **REF 3028** – 5 L

AlproSept-HDE/ AlproSept-HDE gel

- Dezinfectarea mâinilor, precum și dezinfectarea pielii înainte de efectuarea injecțiilor obișnuite și perforarea vaselor periferice.
- Gelul AlproSept-HDE și AlproSept-HDE au o toleranță cutanată deosebit de bună.
- Fără aldehide și fenoli.
- Gelul AlproSept-HDE / HDE se aplică nediluat. •
- Pentru dezinfectarea igienică a mâinilor, frecați 3-5 ml AlproSept-HDE / HDE gel și mențineți umed timp de 30 de secunde.

- ## Eficacitate / Aplicare
  - **bactericid** incl. MRSA și adecvat pentru profilaxia spitalismului
  - • **yeasticida** (C. albicans)
  - • **virusul** care inactivează un spectru limitat de activitate virucidă**: toate virusurile „transmise de sânge”,** precum și adeno-, rota-, noro-virusuri care nu sunt învelite
  - • dovedit conform EN 1500, EN 14476
  - • dezinfectarea igienică a mâinilor: 30 sec.

Ingredient activ

- Etanol, propan-2-ol, substanțe pentru îngrijirea pielii, QAC + alchilamine; HDE gel incl. agent de îngroșare

Delivery form

- **REF 5019** – 1 L AlproSept-HDE
- **REF 3014** – 1 L AlproSept-HDE gel
- **REF 4014** – 1 L Dosage pump

Accessories

REF 3519 – Distribuitor de perete (1 L/500 ml).

ITALCERT

CERTIFICATO N° 505SGQ05

CERTIFICATE N° 505SGQ05

Si certifica che il
this is to certify that

Sistema di Gestione per la Qualità

Quality Management System

messo in atto da
implemented by

APTACA S.p.A.

Via Monte Bianco, 4 – IT 20900 MONZA (MB)

nella Sede Operativa di
Operative Unit

Regione Monforte, 30 – IT 14053 CANELLI (AT)

è conforme alla norma
is in compliance with the standard

UNI EN ISO 9001-2015 (ISO 9001-2015)

per i seguenti Processi
concerning the following kinds of Processes

Gestione della fabbricazione ed immissione in commercio di tamponi sterili per il prelievo di campioni biologici in orifizi naturali e in ambito chirurgico. Progettazione e fabbricazione di dispositivi medico diagnostici per laboratori di analisi. Gestione della fabbricazione ed immissione in commercio di dispositivi medici invasivi in relazione agli orifizi del corpo in Classe I Sterile. Fabbricazione di dispositivi medici invasivi in relazione agli orifizi del corpo in Classe I Sterile. Commercializzazione di dispositivi medici e diagnostici in vitro. Commercializzazione di articoli da laboratorio

Management of the manufacturing and placing on the market of sterile tampons for sampling of biological specimens in natural orifice and in surgical field. Design and manufacturing of diagnostic medical devices for laboratories of analysis. Management of the manufacturing and placing on the market of invasive medical devices with respect to body orifices (class I sterile). Manufacturing of invasive medical devices with respect to body orifices (class I sterile). Marketing of medical and diagnostic devices in vitro. Marketing of laboratory articles.

Il presente Certificato è soggetto al rispetto delle condizioni stabilite dai Regolamenti per la certificazione in vigore applicabili.
This Certificate shall satisfy the requirements established in the Rules for the certification in force applicable.
In caso di discordanza tra le lingue utilizzate nella traduzione del contenuto del presente certificato, fare riferimento alla lingua italiana
In cases of discrepancy between the languages used in the translation of the content of this certificate, please refer to the Italian language.

L'AMMINISTRATORE DELEGATO
MANAGING DIRECTOR

Dr. Ing. Roberto Cusolito

Data di Prima Emissione *First Issue Date*	Data di Prima Emissione ITALCERT *First Issue Date ITALCERT*	Data di Rinnovo *Renewal Date*	Data di Scadenza *Expiration Date*
1998-07-23	2011-10-30	2020-10-30	2023-10-29

Settore IAF 14 - 29

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 023A
Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

ITALCERT S.r.l. | Viale Sarca, 336 – 20126 Milano (MI) | tel. +39 0266104876 | fax. +39 0266101479 | www.italcert.it | italcertsrl@legalmail.it

Nuova Aptaca Srl Regione Monforte, 30 - 14053 Canelli (Asti) Italy
Tel. (+39 0141/83.50.75 – Fax (+39) 0141/83.52.92
E-Mail: info@aptaca.com – Website: www.aptaca.com

CERTIFIED COMPANY UNI EN ISO 9001 & UNI CEI EN ISO 13485

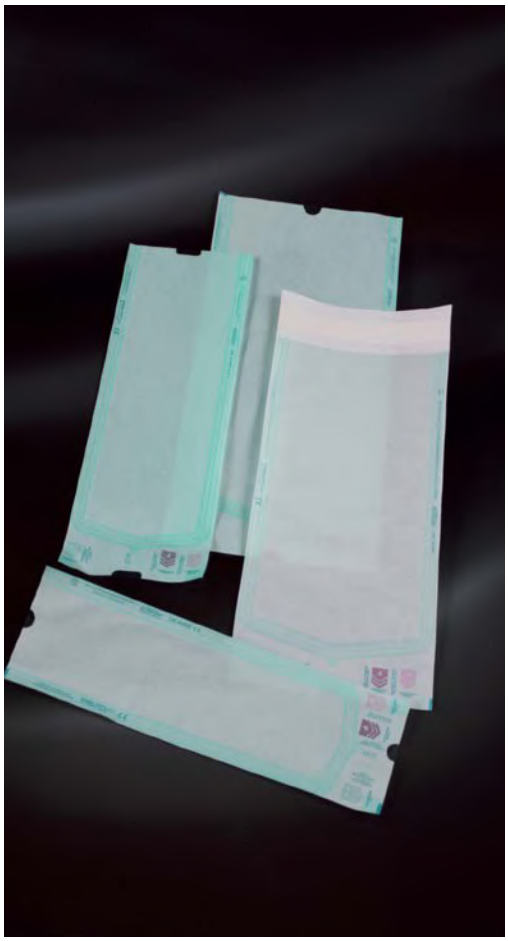
SCHEDA TECNICA PRODOTTO
TECHNICAL DATA SHEET

DATA EMISSIONE / DATE OF ISSUE
05.09.2018

MADE IN ITALY

ARTICOLO: **BUSTE PER STERILIZZAZIONE**
ITEM: ***STERILIZATION POUCHES***

DESCRIZIONE / *DESCRIPTION*



Buste piatte monouso per sterilizzare strumenti chirurgici o altri Dispositivi Medici, mediante EtO o Vapore. Sono prodotte in carta medicale accoppiata con film plastico trasparente, offrono una tenuta costante in fase di sterilizzazione e un'ottima pelabilità in fase di apertura, senza rilascio di fibre della carta o lacerazioni del materiale plastico. Su ogni busta sono stampati tutti i dati utili per garantire l'identificazione e la rintracciabilità. Sono inoltre stampati gli indicatori di viraggio per la sterilizzazione EtO e Vapore, la cui variazione di colore indica che il Dispositivo ha subìto il processo di sterilizzazione. Disponibili anche in versione auto-sigillanti con biadesivo che permette la chiusura delle buste anche in assenza di sigillatrice. Tali Dispositivi sono composti da materiale idonei e appositamente studiati per ottenere un'elevata protezione ai batteri. Conformi alle norme UNI EN 868:5, UNI EN ISO 11607:1-2 e ISO 11140-1, classificate come Dispositivi Medici di Classe I, non sterile (93/42/CE). I Dispositivi sono ottenuti mediante una saldatura a caldo dei film; le linee di saldatura sono multiline, resistenti e uniformi per impedire depositi di polvere e ridurre i rischi di contaminazione del prodotto contenuto nella fase d'apertura o durante la sua conservazione.

Disposable flay pouches for surgical instruments or other Medical Devices sterilization, through EO Gas or Steam. Made in medical paper with transparent plastic film, They offer constant hold during sterilization and excellent peelability during opening, with no paper fibre residue or tearing in the plastic material. On each pouch necessary data are printed for granting identification and traceability. Irreversible radiating indicators for EO and Steam sterilization are as well printed, whose color variation indicates that the Device has undergone the sterilization process. Also available in self-sealing version with double-sides tape that allows the pouches closure as well in absence of sealing machine. These Devices are made of suitable materials specifically designed for achieving high protection against bacteria. Conform to UNI EN 868:5, UNI EN ISO 11607:1-2 and ISO 11140-1norms, classified as Class I Medical Devices, non sterile (93/42/CE). The Devices are obtained by means of film heat sealing, the sealing lines are multiline, resistant and uniform to prevent dust deposits and to reduce the risks of contamination of the contained product during opening or storage.

Prodotto con marchio CE - conforme alla Direttiva 93/42/CE e al D.lgs 46 del 24/02/1997 e s.m.i.

CE Marked product - manufactured in compliance with 93/42/CE Directive and D.lgs 46 dtd 24/02/1997

CARATTERISTICHE PRINCIPALI		*TECHNICAL FEATURES*
Stato microbiologico	**NON STERILE / *NOT STERILE***	*Microbilogical status*
Composizione	*CARTA MEDICALE / FILM PLASTICO TRASPARENTE* *MEDICAL PAPER / TRANSPARENT PLASTIC FILM*	*Composition*
Validità del prodotto	5 ANNI / *YEARS*	*Shelf life*

Nuova Aptaca Srl Regione Monforte, 30 - 14053 Canelli (Asti) Italy
Tel. (+39 0141/83.50.75 – Fax (+39) 0141/83.52.92
E-Mail: info@aptaca.com – Website: www.aptaca.com

Codice Articolo* *Item code**	Dimensioni *Dimensions* (mm)	Tipo *Type*	Confezione Packaging	RDM
16710	75 x 250	Standard	1000 pcs 30 x 25 x 11 cm – 2,4 Kg	67037/R
16711	75 x 400	Standard	1000 pcs 41 x 31 x 10 cm – 2,7 Kg.	67037/R
16712	100 x 250	Standard	1000 pcs 30 x 25 x 11 cm – 3,1 Kg.	67037/R
16713	150 x 300	Standard	1000 pcs 41 x 31 x 10 cm – 5,6 Kg.	67037/R
16714	300 x 500	Standard	500 pcs 56 x 32 x 12 cm – 9,5 Kg.	67037/R
16715	90 x 230 x 40	Auto-sigillante *Self-Sealing*	2400 pcs 32 x 29 x 31 cm – 8,5 Kg.	67037/R
16716	140 x 250 x 40	Auto-sigillante *Self-Sealing*	1600 pcs 32 x 29 x 31 cm – 9,5 Kg.	67037/R
16717	190 x 330 x 40	Auto-sigillante *Self-Sealing*	1200 pcs 41 x 41 x 21 cm – 10,5 Kg.	67037/R
16719	300 x 450 x 40	Auto-sigillante *Self-Sealing*	400 pcs 33 x 56 x 14 cm – 7,0 Kg.	67037/R
16720	300 x 500 x 40	Auto-sigillante *Self-Sealing*	400 pcs 33 x 56 x 14 cm – 7,0 Kg.	67037/R

* Altre misure disponibili su richiesta / *Other sizes available on request*

DESTINAZIONE D'USO / *INTENDED PURPOSE*

La destinazione è quella di "Dispositivo Medico" di Classe I - destinati a Operatori Sanitari che necessitano di sterilizzare strumenti chirurgici o altri Dispositivi Medici/Dispositivi Medico diagnostici in Vitro mediante gas EtO o Vapore.
Il dispositivo in oggetto è destinato esclusivamente ad uso professionale.

Classificazione Nazionale Dispositivi Medici (CND) > S01010101 (Buste piatte in accoppiato carta/film plastico per sterilizzazione)
Classificazione GMDN > 13735 (sterilization packaging, single-use). A device intended to be used to enclose medical devices that are to be sterilized. It is designed to allow sterilization of the enclosed medical device and also to maintain sterility of the device until the packaging is opened for use of the device, or until a predetermined shelf date is expired. This is a single-use device.

This product is intended as "Medical Device" Class I not sterile. These Medical Devices are intended for Health Operators needing to sterilize surgical instruments or other Medical Devices/In Vitro Medical Device using EO or Steam.
This device is for professional use only.

National classification of medical devices (CND - For Italian law) > *S01010101 (Sterilization flat pouches, paper/plastic film)*
GMDN > *13735 (sterilization packaging, single-use). A device intended to be used to enclose medical devices that are to be sterilized. It is designed to allow sterilization of the enclosed medical device and also to maintain sterility of the device until the packaging is opened for use of the device, or until a predetermined shelf date is expired. This is a single-use device.*

Nuova Aptaca Srl Regione Monforte, 30 - 14053 Canelli (Asti) Italy
Tel. (+39 0141/83.50.75 – Fax (+39) 0141/83.52.92
E-Mail: info@aptaca.com – Website: www.aptaca.com

AVVERTENZE / *WARNINGS*

Le buste sono Dispositivi Medici di "lungo termine" destinati ad essere utilizzati di norma per una durata continua di 30 giorni, poiché i Dispositivi in questione sono fabbricati appositamente per garantire e mantenere la sterilità del prodotto contenuto per diversi anni, se conservati in modo adeguato.

Sterilization pouches are "long term" Medical Devices normally used for a continuous period of 30 days, because these Devices are specially made to ensure and maintain the sterility of the contained product for a number of years, if stored properly.

COMPOSIZIONE / *COMPOSITION*

CARTA MEDICALE / *MEDICAL PAPER*

Carta medicale 60g/m^2 è conforme alle norme UNI EN 868:5, UNI EN ISO 11607:1-2 e ISO 11140-1 ed è fabbricata in accordo alla norma UNI EN ISO 9001 e UNI EN ISO 14485.
La carta medicale è resistente all'umidità e possiede un grado di porosità che la rende idonea alla sterilizzazione EtO (gas) e alla sterilizzazione a Vapore (Steam). Presenta un'elevata barriera ai batteri. Indicata come supporto per stampa di tipo flesso grafico e a rotocalco.
Grammatura: 60 g/m^2

Medical Paper 60g/m^2 is conform to standards UNI EN 868:5, UNI EN ISO 11607:1-2 e ISO 11140-1 and is manufactured in compliance with UNI EN ISO 9001 and UNI EN ISO 14485.
Medical Paper is humidity-resistance and have a degree of roughness that made it suitable to EO (gas) and Steam sterilization. It present hight bacterial barrier. Is indicated as a support for flex graphic and rotogravure printing.
Paper Grammage: 60 g/m^2

PROPERTIES	UNITS	STANDARDS	TYPIC
SUBSTANCE	g/m²	ISO 536	60,00
BENDTSEN POROSITY	ml/mn	ISO 5636-3	1 000
AIR PERMEANCE	µm(Pa.s)	ISO 5636-3	11,40
BENDTSEN ROUGHNESS FS	ml/mn	ISO 8791-2	375
BENDTSEN ROUGHNESS WS	ml/mn	ISO 8791-2	375
PORE SIZE	µm	EN 868-2:2009(app. E)	21,0
THICKNESS	µm	ISO 534	83,0
TENSILE STRENGHT MD	kN/m	ISO 1924-2	6,40
TENSILE STRENGHT CD	kN/m	ISO 1924-2	3,40
WET TENSILE STRENGHT MD	kN/m	ISO 3781	2,10
WET TENSILE STRENGHT CD	kN/m	ISO 3781	1,10
BURST STRENGHT	kPa	ISO 2758	350
WET BURST	kPa	ISO 3689	150
TEARING STRENGHT MD	mN	ISO 1974	600
TEARING STRENGHT CD	mN	ISO 1974	650
COBB TEST (60 S)	g/m²	ISO 535	15,0
WATER REPELLENCY	s	EN 868-2:2009(app. D)	35
FLUORESCENCE	pts/dm²	EN 868-2:2009(app. B)	0,0

Nuova Aptaca Srl Regione Monforte, 30 - 14053 Canelli (Asti) Italy
Tel. (+39 0141/83.50.75 – Fax (+39) 0141/83.52.92
E-Mail: info@aptaca.com – Website: www.aptaca.com

FILM PLASTICO TRASPARENTE / *TRANSPARENT PLASTIC FILM*

Il film medicale laminato PET 12 / PP 40 è composto da una pellicola di Polietilene tereftalato (Poliestere) e da una pellicola di Polipropilene. L'adesivo frapposto ai due film non contiene solvente, pertanto il prodotto ottenuto è privo di ritenzione solvente.
Il film PET12 / PP40 è fabbricato conformemente alle norme UNI EN 868:5, UNI EN ISO 11607:1-2 e ISO 11140-1 e alla Direttiva 94/62/CE del Parlamento Europeo e del Consiglio, del 20 dicembre 1994, sugli imballaggi e i rifiuti di imballaggio.
Spessore nominale: 52 micron ±10%

The laminated medical PET 12 / PP40 film is made up of a film of polyethylene terephthalate (polyester) and a film of polypropylene. The adhesive between the two films does not contain solvent, therefore, there is no solvent retention in the finished product.
The PET12 / PP40 film is manufactured in compliance with UNI EN 868:5, UNI EN ISO 11607:1-2 and ISO 11140-1 standards and Directive 94/62/EC of the European Parliament and Council of 20 December 1994, regarding packaging and packaging waste.
Nominal thickness: 52 micron ±10%

PROPERTIES	UNITS	METHOD	TYPIC
THICKNESS	µm	-	52
BASE WEIGHT	g/m²	-	54
WATER VAPOUR PERMEABILITY	g/m²/24h	ASTM F 1249-38°C- 90% RH	6,0
OXYGEN PERMEABILITY	cc/m²/24h	ASTM D 3985- 23°C- 0% RH	125

AVVERTENZE PER L'USO / *OPERATING INSTRUCTIONS*

Non avvicinare il dispositivo alla fiamma o a fonti di calore che lo potrebbero danneggiare.
Keep out of flame or heat sources which might damage the product

Non utilizzare il prodotto scaduto o con la confezione aperta
Do not use after expiry date or if packing is opened

Non variare la destinazione d'uso
Do not vary the intended purpose of the product

Prodotto non adatto ai bambini
Keep out of reach of children

Conservare in luogo asciutto, Temperatura min -10°C max +30°C - Umidità relativa 40 - 60% HR
Store in dry place, Temperature range: min -10°C max +30°C - Relative humidity 40 - 60% HR

Smaltimento: utilizzare gli appositi D.P.I e smaltire secondo le normative vigenti
Disposal: use appropriate personal protective equipment and act according to applicable regulations

Prima dell'utilizzo con sostanze particolari consultare sul catalogo le tabelle di resistenza/compatibilità dei materiali.
Before use with particular substance check the resistance / compatibility chart on our catalogue

SWABS WOODEN STICK

Cotton swabs with wooden stick. Length 150 mm.

Cod.	Description
5100/SG/CS	Sterile - Ind. wrapped