

Ministero della Salute

DGFDH

0029415-P-28/07/2010

I.S.I.e.1/2010/390



73902501



Ministero della Salute

DIPARTIMENTO DELL'INNOVAZIONE
DIREZIONE GENERALE DEI FARMACI E DISPOSITIVI MEDICI
UFFICIO III

DGFDH/III/P. I.S.I.e.1/2010/390

HAVING REGARD to the 93/42/EEC Directive concerning medical devices;

HAVING REGARD to the Legislative Decree (D.L.vo) n. 46/97 (and its following amendments) reporting the accomplishment of 93/42 EEC Directive;

HAVING REGARD to request dated July 05, 2010, Reference nr. 27631-A-14/07/2010, submitted by the Company SVAS BIOSANA S.r.l., located in Via M. Perillo 34, 80047 S. Giuseppe Vesuviano (NA), Italy, VAT No.01354901215;

WHEREAS this Company paid the fees required by Ministerial Decree (D.M.) May 24, 2004;

HAVING REGARD to the official deeds;

IT IS ATTESTED

That the Company SVAS BIOSANA S.r.l., located in Via M. Perillo 34, 80047 S. Giuseppe Vesuviano (NA), Italy, is the manufacturer and has marked CE as medical device according to the Directive 93/42/EEC, the following product:

Traversa assorbente, mod.: FARMEX

The above mentioned product, according to the art. 4 of the above mentioned Directive, can freely circulate and can be placed on the market in Italy and in all the European Union.

This certificate is issued on the interested party's request in according to the law and for export to Countries outside European Union.

The Office Manager
Dr. Annamaria Donato

Ministerul Sănătății
DGDMSF
0029415-P-28/07/2010
I.5.1.e. 1/2010/390
73602501

Ștampila Ministerului Economiei și Finanțelor

Ministerul Sănătății

DEPARTAMENTUL INVENȚII
DIRECȚIA GENERALĂ DE FARMACIE ȘI DISPOZITIVE MEDICALE
BIROU III

DGFDM/III/P. I.5.1.e.1/2010/390

AVÂND ÎN VEDERE Directiva 93/42/CEE cu privire la dispozitivele medicale;
AVÂND ÎN VEDERE Decretul Legislativ nr. 46/97 și amendamentele următoare de implementare a Directivei 93/42 CEE;
AVÂND ÎN VEDERE solicitarea nr. 27631-A-14/07/2010 din data de 05 Iulie, 2010 depusă de Societatea **SVAS BIOSANA S.p.A.**, cu sediul social înregistrat în Via M. Perillo 34, 80047 S. Giuseppe Vesuviano (NA), Italia, TVA Nr. 01354901215;
ÎNTRUCÂT Societatea a plătit toate taxele cerute prin Decretul Ministerial din 24 Mai, 2004;
AVÂND ÎN VEDERE documentele oficiale;

SE CERTIFICĂ PRIN PREZENTA

că, în conformitate cu Directiva 93/42 CEE, Societatea **SVAS BIOSANA S.p.A.**, cu sediul social înregistrat în Via M. Perillo 34, 80047 S. Giuseppe Vesuviano (NA), Italia, este producătorul următorului dispozitiv medical marcat CE:

Cearceaf absorbant, mod.: FARMEX

În conformitate cu art. 4 din Directiva 93/42/CEE mai sus menționatul produs poate să circule liber și poate fi pus pe piața din Italia și pe toate piețele din Uniunea Europeană.
Prezentul document a fost emis cererea părții interesate în conformitate cu legea privind exportul în Țări care nu fac parte din Uniunea Europeană.

Șef Birou

Annamaria Donato

Ștampila și semnătura – indescifrabil



Milano, 20/12/2017

Ing. Giovanna Angelillo
SVAS BIOSANA S.p.a.
Via Genio Militare, 40
80044 Ottaviano NA

Ns. rif.: 6062/2017-FG

Oggetto: Certificazione di Conformità del Vs. Sistema di Gestione UNI EN ISO 9001:2015 - ns.
Rif DM-093/09

Con la presente abbiamo il piacere di trasmetterVi

“CERTIFICATO N° 442SGQ09”
UNI EN ISO 9001:2015

rinnovato dal Sottocomitato Tecnico Scientifico di Sistema di “ITALCERT” ed attestante la conformità del Sistema di Gestione adottato presso la Vs. Sede.

Vi ricordiamo che l'utilizzo del marchio ITALCERT è soggetto alle prescrizioni contenute nel Documento R-002 “Regolamento per l'utilizzo del marchio ITALCERT da parte di Aziende con Certificazione di Sistema Qualità” già in Vs. mani e visionabile sul sito internet www.italcert.it. In particolare Vi segnaliamo che qualsiasi utilizzo difforme da quanto previsto dal Regolamento stesso deve essere autorizzato da ITALCERT.

Il presente certificato annulla e sostituisce il precedente n° 442SGQ08 (e allegati).

Cordiali saluti.


ITALCERT S.r.l.
Francesca Grossoni
Settore Certificazione
Sistemi di Gestione

All.c.s.

CERTIFICATO N° 442SGQ09

CERTIFICATE N° 442SGQ09

Si certifica che il
this is to certify that

Sistema di Gestione per la Qualità

Quality Management System

messo in atto da
implemented by

SVAS BIOSANA S.p.A.

Via M. Perillo, 34 - IT 80047 SAN GIUSEPPE VESUVIANO (NA)

Nelle Strutture Operative di cui in allegato 1 al presente Certificato e per le attività elencate

In the Operative Units as per Annex 1 of this Certificate and for the indicated activities

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

Progettazione, produzione e distribuzione, anche a domicilio, di dispositivi medici: dispositivi di protezione e ausili per l'incontinenza, dispositivi per medicazioni generali e specialistiche. Progettazione ed erogazione di servizi di assistenza domiciliare per la fornitura di dispositivi medici. Erogazione di servizi di relazione con il cliente, il consumatore ed il cittadino, attraverso centri di contatto, compresi Call Center. Commercializzazione di dispositivi medici: dispositivi da somministrazione, prelievo e raccolta, dispositivi per medicazioni generali e specialistiche, dispositivi di protezione e ausili per incontinenza. Produzione e commercializzazione di articoli sanitari vari, presidi medico-chirurgici, preparati galenici, medicinali per uso umano e veterinario. Progettazione e produzione di dispositivi medici: dispositivi da somministrazione, prelievo e raccolta, dispositivi per medicazioni generali e specialistiche, sistemi e kit completi per campo operatorio, sistemi completi per aspirazione chirurgica, teli e accessori per campo operatorio, dispositivi per apparato urogenitale, dispositivi crioterapici e ghiaccio istantaneo.

Progettazione e produzione di dispositivi medici: ovatta di cotone idrofilo.

Progettazione ed erogazione del servizio di gestione e conduzione di centrali di sterilizzazione.

Design, production and distribution, also at home, of medical devices: protection devices and incontinence aids, devices for general and specialist dressings. Design and provision of home care services for the supply of medical devices. Provision of relationship services with the customer, the consumer and the citizen, through contact centers, including call centers. Marketing of medical devices: devices for administration, sampling and collection, devices for general and specialist dressings, protection devices and incontinence aids. Production and marketing of various sanitary articles, medical-surgical devices, galenic preparations, medicines for human and veterinary use. Design and production of medical devices: devices for administration, sampling and collection, devices for general and specialist medication, systems and complete kits for operating fields, complete systems for surgical suction, towels and accessories for operating field, devices for urogenital apparatus, cryotherapy devices and instantaneous ice. Design and production of medical devices: cotton wool. Design and provision of service for the management and operation of sterilization centers.

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 rule for the certification in force applicable.

Il presente Certificato deve essere reso pubblico solo in forma integrale completo dell'Allegato 1

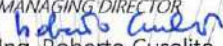
This Certificate should be made public only in integral form complete Annex 1

In caso di discordanza tra le lingue utilizzate nella traduzione del contenuto del presente certificato, fare riferimento alla lingua italiana

In case of discrepancies 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

2003-02-27

Data di Prima Emissione ITALCERT
First Issue Date ITALCERT

2009-10-12

Data di Rinnovo
Renewal Date

2017-12-19

Data di Scadenza
Expiration Date

2020-12-18

Settore IAF 14 - 29 - 35 - 04



SGQ N° 023A PRO N° 122B
SGA N° 020D ISP N° 075E
PRS N° 097C

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

Allegato 1 al Certificato n° 442SGQ09
Annex 1 of Certificate 442SGQ09

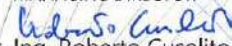
Divisione	Indirizzo Sede	Oggetto
DIVISIONE FARMEX	Via Colle, 104 – IT 80049 SOMMA VESUVIANA NA	Progettazione, produzione e distribuzione, anche a domicilio, di dispositivi medici: dispositivi di protezione e ausili per l'incontinenza, dispositivi per medicazioni generali e specialistiche. Progettazione ed erogazione di servizi di assistenza domiciliare per la fornitura di dispositivi medici. Erogazione di servizi di relazione con il cliente, il consumatore ed il cittadino, attraverso centri di contatto, compresi Call Center. <i>Design, production and distribution, even at home, of medical devices: protective devices and incontinence aids; devices for general and specialist dressings. Design and provision of home care services and after-sales services for the supply of medical devices. Provision of relationship services with customers, consumers and citizens, through contact centers, including Call Center.</i>
DIVISIONE SVAS	Via Trentola, 7 – IT 80049 SOMMA VESUVIANA NA Via Genio Militare, Località Pentelete – IT 80044 OTTAVIANO NA	Commercializzazione di dispositivi medici: dispositivi da somministrazione, prelievo e raccolta, dispositivi per medicazioni generali e specialistiche, dispositivi di protezione e ausili per incontinenza. Commercializzazione di articoli sanitari vari, presidi medico-chirurgici, preparati galenici, medicinali per uso umano e veterinario. <i>Marketing of medical devices: devices for administration, collecting and picking; protection devices and incontinence aids; devices for general and specialist dressings. Marketing of various sanitary ware, medical-surgical supplies, galenic preparations, medicinal products for human and veterinary use.</i>
DIVISIONE MEDICAL	Via Trentola, 7 – IT 80049 SOMMA VESUVIANA NA Via Genio Militare, Località Pentelete – IT 80044 OTTAVIANO NA	Progettazione e produzione di dispositivi medici: dispositivi da somministrazione, prelievo e raccolta, dispositivi per medicazioni generali e specialistiche, sistemi e kit completi per campo operatorio, sistemi completi per aspirazione chirurgica, teli e accessori per campo operatorio, dispositivi per apparato urogenitale, dispositivi crioterapici e ghiaccio istantaneo. Produzione e commercializzazione di articoli sanitari vari. <i>Design and production of medical devices: devices for administration, collecting and picking; devices for general and specialist dressings; systems and operating packs for surgery site; complete systems for surgical aspiration; towels and accessories for surgery site; devices for urogenital apparatus, cryotherapy devices and instant ice. Production and marketing of various sanitary.</i>
DIVISIONE FARMEX	Via Colle, 104 – IT 80049 SOMMA VESUVIANA NA	Progettazione e produzione di dispositivi medici: ovatta di cotone idrofilo. Produzione di articoli sanitari vari. <i>Design and production of medical devices: hydrophilic cotton wool. Production of various sanitary.</i>
Centrale di Sterilizzazione	Azienda Ospedaliera Sant'Anna e San Sebastiano Via F. Palasciano – IT 81100 CASERTA CE	Progettazione ed erogazione del servizio di gestione e conduzione di centrali di sterilizzazione. <i>Design and supply of management and conduction service for sterilization centre.</i>
Centrale di Sterilizzazione	Ente Ospedaliero Regionale MIULLI Strada Provinciale, 127 IT 70021 Acquaviva delle Fonti BA	Progettazione ed erogazione del servizio di gestione e conduzione di centrali di sterilizzazione. <i>Design and supply of management and conduction service for sterilization centre.</i>

La validità del presente Allegato è vincolata a quella del Certificato N 442SGQ09
The validity of this Annex is bound to the Certificate N 442SGQ09

2017-12-19

L'AMMINISTRATORE DELEGATO

MANAGING DIRECTOR


Dr. Ing. Roberto Cusolito

Settore IAF 14 – 29 – 35 – 04


SGQ N° 023A PRD N° 122B
SGA N° 020D ISP N° 075E
PRS N° 097C

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

Milano, 20/12/2017

Ing. Giovanna Angelillo
SVAS BIOSANA S.p.a.
Via Genio Militare, 40
80044 Ottaviano NA

Ns. rif.: 6063/2017-FG

Oggetto: Certificazione di Conformità del Vs. Sistema di Gestione UNI CEI EN ISO 13485:2012 - ns. Rif DM-093/09

Con la presente abbiamo il piacere di trasmetterVi

“CERTIFICATO N° 442DM08”
UNI CEI EN ISO 13485:2012

rinnovato dal Sottocomitato Tecnico Scientifico di Sistema di “ITALCERT” ed attestante la conformità del Sistema di Gestione adottato presso la Vs. Sede.

Vi ricordiamo che l'utilizzo del marchio ITALCERT è soggetto alle prescrizioni contenute nel Documento R-002 “Regolamento per l'utilizzo del marchio ITALCERT da parte di Aziende con Certificazione di Sistema Qualità” già in Vs. mani e visionabile sul sito internet www.italcert.it. In particolare Vi segnaliamo che qualsiasi utilizzo difforme da quanto previsto dal Regolamento stesso deve essere autorizzato da ITALCERT.

Vi preghiamo di notare che: in data 2016-03-01 ISO ha pubblicato la nuova versione della norma ISO 13485:2016; perciò le aziende avranno tre anni per adeguarsi alla nuova edizione della norma; le certificazioni secondo la precedente norma ISO 13485:2003 (UNI CEI EN ISO 13485:2012) saranno quindi valide fino al 2019-02-28.

Il presente certificato annulla e sostituisce il precedente n° 442DM07 (e allegati).

Cordiali saluti.


ITALCERT S.r.l.
Francesca Grosson
Settore Certificazione
Sistemi di Gestione

All.c.s.

CERTIFICATO N° 442DM08

CERTIFICATE N° 442DM08

Si certifica che il

this is to certify that

Sistema di Gestione per la Qualità

Quality Management System

messo in atto da

implemented by

SVAS BIOSANA S.p.A.

Via Perillo, 34 - IT 80047 S.GIUSEPPE VESUVIANO (NA)

**Nelle Strutture Operative di cui in allegato 1 al presente Certificato
e per le attività elencate**

In the Operative Units as per Annex 1 of this Certificate and for the indicated activities

è conforme alla norma

is in compliance with the standard

UNI CEI EN ISO 13485-2012 (ISO 13485-2003)

per i seguenti Processi

concerning the following kinds of Processes

Progettazione, produzione, e distribuzione, anche a domicilio, di dispositivi medici:

dispositivi di protezione e ausili per l'incontinenza, dispositivi per medicazioni generali e specialistiche

Commercializzazione di dispositivi medici: dispositivi da somministrazione, prelievo e raccolta,

dispositivi per medicazioni generali e specialistiche, dispositivi di protezione e ausili per incontinenza.

Progettazione e produzione, di dispositivi medici: dispositivi da somministrazione, prelievo e raccolta, dispositivi per medicazioni generali e specialistiche, sistemi e kit completi per campo operatorio, sistemi completi per aspirazione chirurgica, teli e accessori per campo operatorio, dispositivi per apparato urogenitale, dispositivi crioterapici e ghiaccio istantaneo.

Progettazione e produzione e di dispositivi medici: ovatta di cotone idrofilo.

Progettazione ed erogazione del servizio di gestione e conduzione di centrali di sterilizzazione

Design, production, and distribution, even at home, of medical devices: protection devices and incontinence aids, devices for general and specialist dressings.

Marketing of medical devices: devices for administration, collection and sampling, devices for general dressings

and specialist, protective devices and incontinence aids. Design and production, of medical devices: devices for administration, collection and sampling,

devices for general and specialist dressings, complete systems and kits for the operating field, complete systems for surgical suction,

towels and accessories for the operating field, devices for urogenital apparatus, devices cryotherapy and instant ice.

Design, production and medical devices: cotton wool wadding.

Design and provision of the service for the management and operation of sterilization centers.

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 Rule for the certification in force applicable.

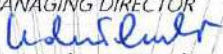
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In case of discrepancies between the languages used in the translation of the content of this certificate, please refer to the Italian language

L'AMMINISTRATORE DELEGATO

MANAGING DIRECTOR


Dr. Ing. Roberto Cusolito

Data di Prima Emissione

First Issue Date

1997-06-23

Data di Prima Emissione ITALCERT

First Issue Date ITALCERT

2009-10-12

Data di Rinnovo

Renewal Date

2017-12-19

Data di Scadenza

Expiration Date

2019-02-28



SGQ N° 023A PRD N° 122B
SGA N° 020D ISP N° 075E
PRS N° 097C

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

Allegato 1 al Certificato n° 442DM08
Annex 1 of Certificate 442DM08

Divisione	Indirizzo Sede	Oggetto
DIVISIONE FARMEX	Via Colle, 104 – IT 80049 SOMMA VESUVIANA NA	Progettazione, produzione e distribuzione, anche a domicilio, di dispositivi medici: dispositivi di protezione e ausili per l'incontinenza, dispositivi per medicazioni generali e specialistiche. <i>Design, production and distribution, even at home, of medical devices: Protective devices and incontinence aids; devices for general and specialist dressings.</i>
DIVISIONE SVAS	Via Trentola, 7 – IT 80049 SOMMA VESUVIANA NA Via Genio Militare, Località Pentelete – IT 80044 OTTAVIANO NA	Commercializzazione di dispositivi medici: dispositivi da somministrazione, prelievo e raccolta, dispositivi per medicazioni generali e specialistiche, dispositivi di protezione e ausili per incontinenza. <i>Marketing of medical devices: devices for administration, collecting and picking; protection devices and incontinence aids; devices for general and specialist dressings.</i>
DIVISIONE MEDICAL	Via Trentola, 7 – IT 80049 SOMMA VESUVIANA NA Via Genio Militare, Località Pentelete – IT 80044 OTTAVIANO NA	Progettazione e produzione di dispositivi medici: dispositivi da somministrazione, prelievo e raccolta, dispositivi per medicazioni generali e specialistiche, sistemi e kit completi per campo operatorio, sistemi completi per aspirazione chirurgica, teli e accessori per campo operatorio, dispositivi per apparato urogenitale, dispositivi crioterapici e ghiaccio istantaneo. <i>Design and production of medical devices: devices for administration, collecting and picking; devices for general and specialist dressings; systems and operating packs for surgery site; complete systems for surgical aspiration; towels and accessories for surgery site; devices for urogenital apparatus, cryotherapy devices and instant ice.</i>
DIVISIONE FARMEX	Via Colle, 104 – IT 80049 SOMMA VESUVIANA NA	Progettazione e produzione di dispositivi medici: ovatta di cotone idrofilo. <i>Design and production of medical devices: hydrophilic cotton wool.</i>
Centrale di Sterilizzazione	Azienda Ospedaliera Sant'Anna e San Sebastiano Via F. Palasciano – IT 81100 CASERTA CE	Progettazione ed erogazione del servizio di gestione e conduzione di centrali di sterilizzazione. <i>Design and supply of management and conduction service for sterilization centre.</i>
Centrale di Sterilizzazione	Ente Ospedaliero Regionale MIULLI Strada Provinciale, 127 IT 70021 Acquaviva delle Fonti BA	Progettazione ed erogazione del servizio di gestione e conduzione di centrali di sterilizzazione. <i>Design and supply of management and conduction service for sterilization centre.</i>

La validità del presente Allegato è vincolata a quella del Certificato N 442DM08
The validity of this Annex is bound to the Certificate N 442DM08

2017-12-19

L'AMMINISTRATORE DELEGATO
MANAGING DIRECTOR


Dr. Ing. Roberto Cusolito



SGQ N° 023A PRD N° 122B
SGA N° 020D ISP N° 075E
PRS N° 097C

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



FARMEX



Adult incontinence devices



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About FARMEX Division	4
Product Identification Guide	6
Features and benefits of Farmex incontinence products	7

Farmex Standard Products

Adult Diaper	8
Shaped Diaper	9
Rectangular Pad	9
Absorbent Underpad	10
Elastic Panties	10
Lady Light Incontinence	11
Man Light Incontinence	11

Farmex Airdermo Products (breathable with derma-protection)

Adult Diaper	13
Shaped Diaper	13

Farmex Air Products (breathable)

Pants	14
Belt	14

Body Wash

Soft wipes	15
Fluff wipes	16
Bibs with pocket	16
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About Svas Biosana



SVAS BIOSANA S.p.A.

was founded in 1972 as a trading company specializing in the medical devices distribution. Thanks to the commitments of its Management, the company grew steadily and soon became an important point of reference in Italy and abroad for the healthcare industry. Over time, the company develops an “ industrial “ project, acquiring the technical skills required to manufacture products under its own brand. This project has materialized with the creation of industrial divisions engaged in different lines of products. In 2002, Svas Biosana started a “ Research & Development “ Chemical –Microbiological Laboratory,





in which an efficient team of professionals carries out activities of studying, characterization and testing of new materials and products.

Svas Biosana S.p.A., boasts today, an established Quality Management System according with ISO 9001 and 13485, and a multi-divisional structure, designed to enhance the level of specialization of the individual areas:

• Svas Division

• Farmex Division

• Medical Division

About Farmex Division

Svas Biosana, thanks to FARMEX DIVISION, has offered a concrete, practical and effective response to the incontinence problem from over 30 years.

Adult incontinence line provides a wide range of reliable and functional devices able to meet the patients needs with specific solutions to every incontinence level.

Farmex Division has always invested his energies into the acquisition of partners who provide the highest reliability, by purchasing raw materials of excellent quality and implementing its technological structure with advanced equipments.



Quality and Certificates

Svas Biosana Quality systems are an integral part of our business practices. Svas Biosana Farmex Division is committed to comply with the requirements of UNI EN ISO 9001:2008, UNI EN ISO 13485:2004 also committed to continually improve the effectiveness of our quality systems. Our medical devices are in conformity with the requirements of the directive 93/42/CEE and are periodically tested by accredited laboratories.

Thanks to a quality systems carried out through the adoption and the continual improvement of a suitable organization structure, Svas Biosana wants to achieve following objectives:

- To enhance customer satisfaction by consistently providing a quality of service that meets or exceeds customer expectations.
- To ensure the continued development, implementation and maintenance of the quality system and to continually seek improvements in the effectiveness of the quality system.
- To improve effectiveness and efficiency in our business processes.

Svas Biosana recognizes that future is critically dependent on our customers satisfaction and to that end it is our policy to establish mutually beneficial relationships with customers, suppliers and other stakeholders to enhance our ability to create value.



Product Identification Guide

Farmex Incontinence Devices

FARMEX
Standard products

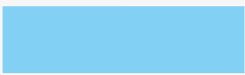
FARMEX AIR DERMO
Breathable with
Derma-protection products

FARMEX AIR
Breathable products

(Degrees of incontinence)

Absorbency level

Farmex proposes 4 different absorbency levels, identified by:
Name (A), Color Code (B), Drops number (C).

A	PLUS	EXTRA	SUPER	MAXI
B				
C				
	moderate	medium / heavy	heavy	very heavy

Sample pack



FARMEX

Features and benefits of Farmex incontinence products

The importance of taking care of the patients and the importance of providing a product able to meet concret needs of the patients have promoted the development and the realization of our adult diaper with printed PE film for underline absorbency level identification. In fact the new identification system of the product according to absorbency level is easy to use for both patients and care staff.

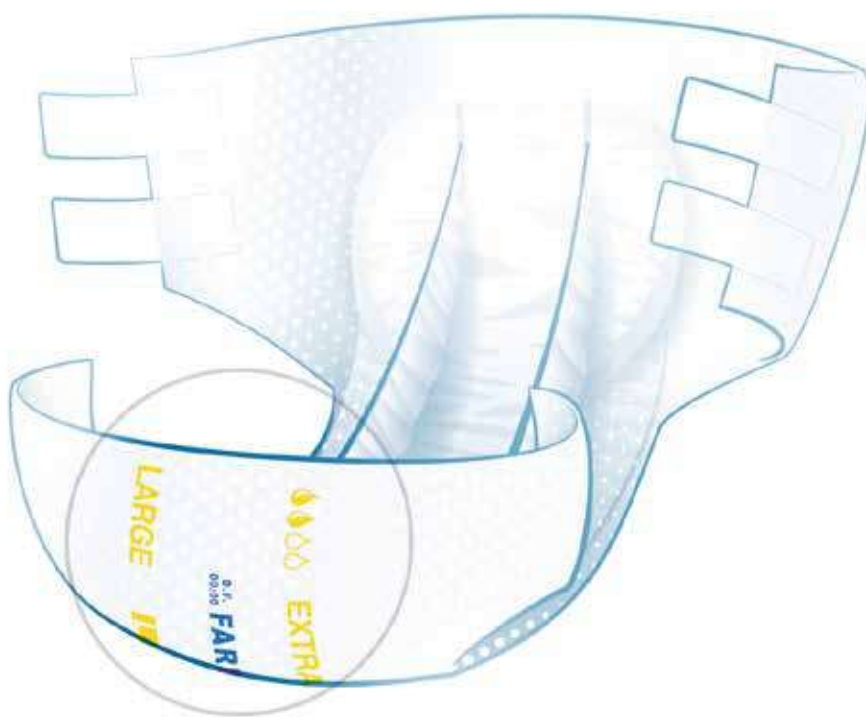
Our four different absorbency levels are identifiable by the color code and drops number printed.

Printing on the adult diaper device offers further informations:

Color Code printing: Absorbency Level

Drawing Printing: Device Size / Drops according absorbency level

Wetness indicator: Lot number and manufacture date discoloring enables the patient or care staff to establish how much of a device's total capacity has been used.



Our adult incontinence devices are:

- Hypoallergenic
- Clinically Tested
- Latex Free
- Odor control:

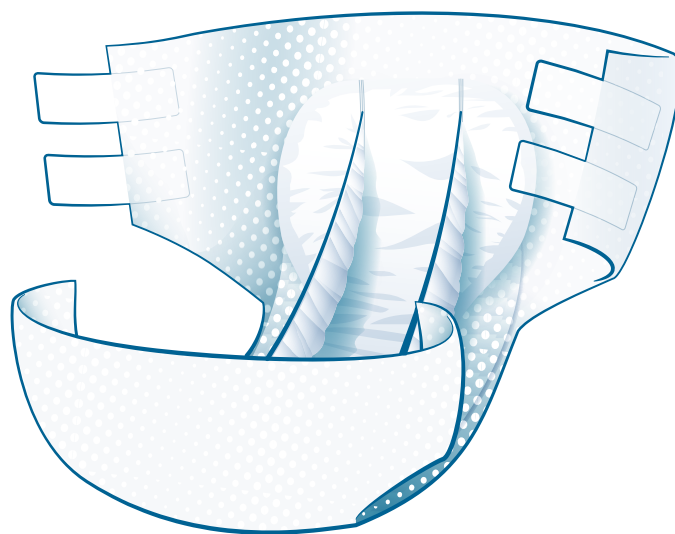
Reduces the risk of unpleasant odours.



Farmex® Adult Diaper

This device is suitable for protection and care of people with moderate to heavy incontinence. It is anatomically shaped with barrier to the liquids. Through the fastening of four refastenable tapes and the presence of longitudinal elastics, when the patient wears it, this device takes the shape of panties. The external side is made of soft, non-toxic and waterproof polyethylene with a wetness indicator for easy product identification. The absorbent core is composed of pure fluff pulp and SAP superabsorbent polymers. It is also coated with a special filter fabric that accelerates the spread of liquids and helps their retention. A layer of hypoallergenic non-woven fabric cover the whole inner surface.

(Suitable both for bedridden and not self-reliant people.)

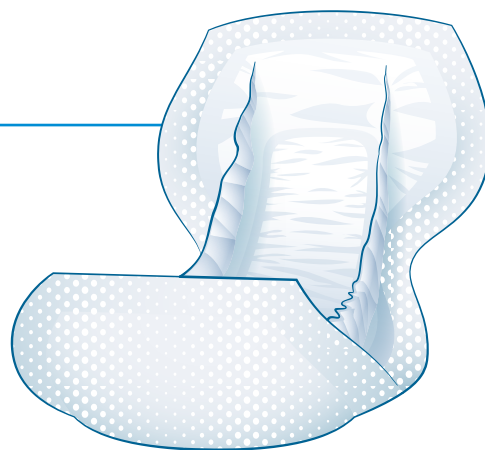


Ref	Ean	Paraph	N.T.N.	Size	Absorb.	Drops	Pcs/Pack	Pcs/Cart.
03JOL3103020	8004007310324	931436808	RIC. 09.30.04.006	M	PLUS		30	90
03JOL3103030	8004007310331	931436834	RIC. 09.30.04.003	L			30	90
03JOL3201510	8004007320019	931436846	09.30.04.009	S	EXTRA		15	90
03JOL3203020	8004007320323	931436911	09.30.04.006	M			30	90
03JOL3203030	8004007320330	931436935	09.30.04.003	L			30	90
03JOL3203040	8004007320347	931436947	RIC. 09.30.04.003	XL			30	90
03JOL3303020	8004007330322	932229824	RIC. 09.30.04.006	M	SUPER		30	90
03JOL3303030	8004007330339	932229836	RIC. 09.30.04.003	L			30	90
03JOL3302440	8004007330544	931437002	RIC. 09.30.04.003	XL			24	72
03JOL3402220	8004007340420	931437038	RIC. 09.30.04.006	M	MAXI		22	66
03JOL3402230	8004007340437	931437040	RIC. 09.30.04.003	L			22	66

Farmex® Shaped Diaper

This device is suitable for protection and care of people with light and moderate incontinence problems. Its anatomical shape, with barrier to the liquids, offers exceptional wearability and practical use together with separate fastening system. The external side is made of soft, non-toxic and waterproof polyethylene with a wetness indicator for easy product identification. The absorbent core is composed of pure fluff pulp and SAP superabsorbent polymers. It is also coated with a special filter fabric that accelerates the spread of liquids and helps retention. A layer of hypoallergenic non woven fabric covers the whole inner surface.

(Suitable both for bedridden and walking people.)



Ref	Ean	Paraph	N.T.N.	Absorb.	Drops	Pcs/Pack	Pcs/Cart.
03JOL2102000	8004007210204	931093468	09.30.04.018	PLUS	3	20	80
03JOL2202000	8004007220203	931093470	09.30.04.015	EXTRA	4	20	80
03JOL2302000	8004007230202	931093482	09.30.04.012	SUPER	5	20	80
03JOL2402000	8004007240201	931093494	RIC. 09.30.04.012	MAXI	6	20	80

Farmex® Rectangular Pad

This device is suitable for protection and care of people with moderate incontinence problems, its shape is rectangular with or without barrier to the liquids. Through the use of plastic or elastic panties, this device ensures optimum practical use. The external support is made of soft, non-toxic and waterproof polyethylene. The absorption area is composed of pure fluff pulp, evenly distributed and firmly combined onto the inner layer in order to make everything compact. The hypoallergenic non-woven inner layer covers the whole surface. Its structure allows an efficient retention of the liquids.

(Suitable for bedridden and walking people.)



STANDARD								
Ref	Ean	Paraph	N.T.N.	Type	Absorb.	Drops	Pcs/Pack	Pcs/Cart.
03JOL4103001	8004007410307	931437077	09.30.04.021	with barrier	PLUS		30	180
03JOL4103000	8004007410314	931437103	09.30.04.021	without barrier			30	180
LONG								
Ref	Ean	Paraph	N.T.N.	Type	Absorb.	Drops	Pcs/Pack	Pcs/Cart.
03JOL4103011	8004007410321	931437115	09.30.04.021	with barrier	PLUS		30	150
03JOL4103010	8004007410338	931437127	09.30.04.021	without barrier			30	150

Farmex® Absorbent Underpad

The device is manufactured for all the cases of urinary and fecal incontinence for bedridden patients. It is not wearable, this device may be positioned between the patient and the bed surface in order to ensure the health of people. The external side is made of soft, non-toxic and waterproof polyethylene. The absorption area is composed of pure fluff pulp, evenly and firmly distributed onto the roof to make everything compact. The hypoallergenic non-woven inner layer covers the entire surface. Its structure helps an efficient retention of the liquids.



STANDARD

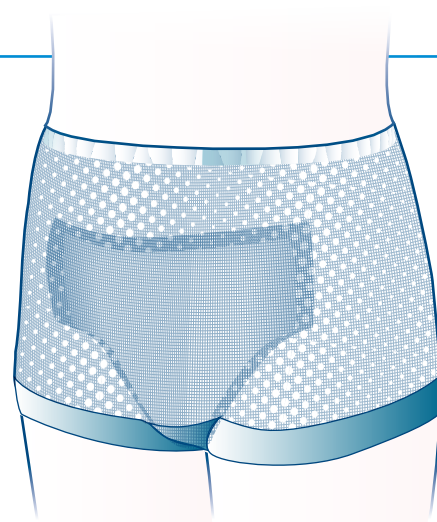
Ref	Ean	Paraph	N.T.N.	Size	Pcs/Pack	Pcs/Cart.
03JOL5001510	8004007500015	931437519	RIC. 18.12.15.006	40 X 60	15	90
03JOL5003020	8004007500329	931437533	RIC. 18.12.15.006	60 X 60	30	90
03JOL5003030	8004007500336	931437560	18.12.15.006	60 X 90	30	90
03JOL5003040	8004007500343	931437584	18.12.15.003	80 X 180 Tuck in panels	30	90

ULTRA

Ref	Ean	Paraph	N.T.N.	Size	Pcs/Pack	Pcs/Cart.
03JOL5023030	03JOL5103030	932230170	RIC. 18.12.15.006	60 X 90	30	90
03JOL5023040	03JOL5103040	932230182	RIC. 18.12.15.003	80 X 180 Tuck in panels	30	90

Farmex® Elastic Panties

This product is particularly suitable for the fastening of diapers (rectangular and shaped) and dressing. Thanks to its flexibility, it keeps the absorption body more adherent and stable without pressing it. It can be washed at 60° and re-used several times.

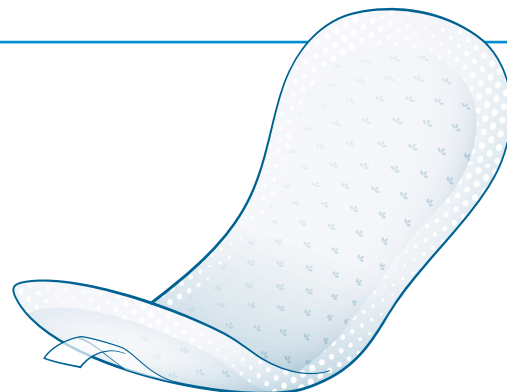


Ref	Ean	Paraph	N.T.N.	Size	Pcs/Pack	Pcs/Cart.
03JOL9600310	8004007960017	932230131	09.30.09.009	SMALL	30 x 3	90
03JOL9600320	8004007960024	932230143	09.30.09.006	MEDIUM	30 x 3	90
03JOL9600330	8004007960031	932230156	09.30.09.003	LARGE	30 x 3	90
03JOL9600340	8004007960048	932230168	RIC. 09.30.09.003	EXTRALARGE	30 x 3	90

Farmex® Lady

Farmex Lady is designed to provide a high absorption capacity and to offer a safe solution to the light incontinence problems. Its soft and filtering multilayer body distributes the liquids evenly onto the whole surface and keeps the skin dry all the time. Farmex Lady diapers are made of fluff pulp and superabsorbent polymers with “OdorFree” the innovative system; the fastening is guaranteed by longitudinal adhesive on the external layer. Furthermore Normal, Extra and Super sizes are wrapped one by one in practical sachets hygienically protected.

(Suitable for people with incontinence problems from mild to moderate grade.)



Ref	Ean	Paraph	N.T.N.	Absorb.	Drops	Pcs/Pack	Pcs/Cart.
03JOL2001210	8004007200700	932229848	RIC. 09.30.04.018	NORMAL	💧💧💧💧	12	144
03JOL2001020	8004007200113	932229851	RIC. 09.30.04.018	EXTRA	💧💧💧💧	10	100
03JOL2003020	8004007200311	932229863	RIC. 09.30.04.018	EXTRA	💧💧💧💧	30	360
03JOL2001030	8004007200120	932229875	RIC. 09.30.04.018	SUPER	💧💧💧💧	10	120
03JOL2003030	8004007200328	932229887	RIC. 09.30.04.018	SUPER	💧💧💧💧	30	180
03JOL2001440	8004007200830	932229899	RIC. 09.30.04.018	SUPER PLUS	💧💧💧💧	14	168

Farmex® Man

Farmex Man is designed specifically for light man incontinence. Optimum comfort and discretion due to the special shape adapted to the male anatomy. A long adhesive strip helps to keep the pad firmly in place, close-fitting underwear. Farmex Man is easy-to-use.



Ref	Ean	Paraph	N.T.N.	Absorb.	Drops	Pcs/Pack	Pcs/Cart.
03JOL9041500	8004007904004	932719709	RIC. 09.30.04.018	SUPER	💧💧💧💧	15	120



Breathable with derma-protection NEW LINE PRODUCTS

The breathable **FARMEX AIR DERMO** products are the result of constant research and development aimed to meet the new requirements of patients with incontinence problems. The new breathable external layer is the most innovative and suitable solution for patients with particularly delicate and sensitive skin who need a softer and dry touch.

These new aids provide air circulation, by preventing the onset of skin complications. Moreover, the new products provide a more comfortable wearability thanks to their softness and absence of any noise.

The special emollient lotion applied on the inner surface in contact with skin gives lenitive properties for sensitive skin.

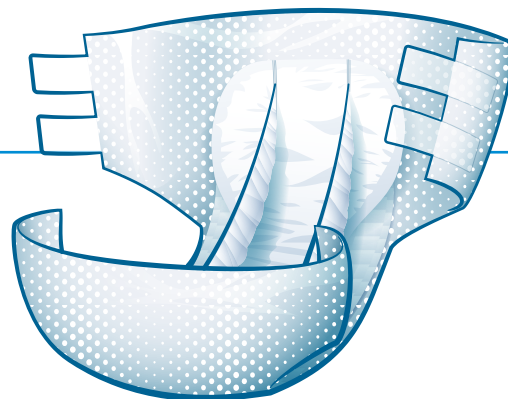
Combination between breathable backsheet and the emollient lotion guarantees to AIR DERMO products an efficient derma-protection system to avoid skin irritation.



Adult Diaper

New **AIR DERMO Adult Diaper** is the most innovation and suitable solution for delicate and very sensitive skin. The special emollient lotion applied on the inner surface in contact with skin gives lenitive properties for sensitive skin. Combination between breathable backsheet and the emollient lotion guarantees to AIR DERMO products an efficient derma-protection system to avoid skin irritation.

(Suitable both for bedridden and not self-reliant people.)



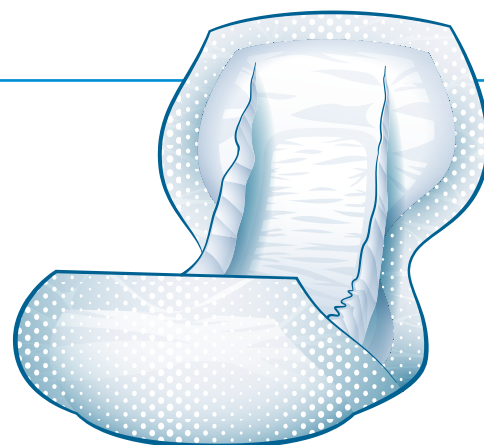
Ref	Ean	Paraph	N.T.N.	Size	Absorb.	Drops	Pcs/Pack	Pcs/Cart.
03JOL3211510	8004007321016	932229901	09.30.04.009	S	EXTRA		15	90
03JOL3213020	8004007321320	932229913	09.30.04.006	M			30	90
03JOL3213030	8004007321337	932229925	09.30.04.003	L			30	90
03JOL3213040	8004007321344	932229937	RIC. 09.30.04.003	XL			30	90
03JOL3313020	8004007331329	932229949	RIC. 09.30.04.006	M	SUPER		30	90
03JOL3313030	8004007331336	932229964	RIC. 09.30.04.003	L			30	90
03JOL3312440	8004007331541	932229976	RIC. 09.30.04.003	XL			24	72
03JOL3412220	8004007341427	932229988	RIC. 09.30.04.006	M	MAXI		22	66
03JOL3412230	8004007341434	932229990	RIC. 09.30.04.003	L			22	66

Shaped Diaper

New **AIR DERMO Shaped Diaper** is the most innovation and suitable solution for delicate and very sensitive skin. The special emollient lotion applied on the inner surface in contact with skin gives lenitive properties for sensitive skin.

Combination between breathable backsheet and the emollient lotion guarantees to AIR DERMO products an efficient derma-protection system to avoid skin irritation.

(Suitable both for bedridden and walking people.)

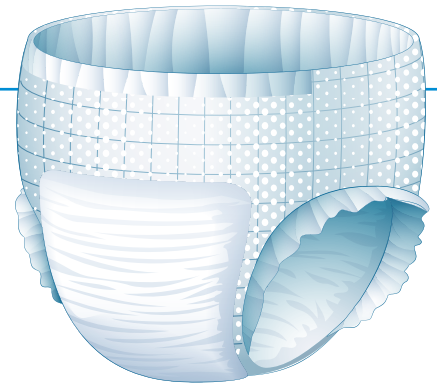


Ref	Ean	Paraph	N.T.N.	Absorb.	Drops	Pcs/Pack	Pcs/Cart.
03JOL2112000	8004007211201	932230004	09.30.04.018	PLUS		20	80
03JOL2212000	8004007221200	932230016	09.30.04.015	EXTRA		20	80
03JOL2312000	8004007231209	932230030	09.30.04.012	SUPER		20	80
03JOL2412000	8004007241208	932230042	RIC. 09.30.04.012	MAXI		20	80

Farmex® Pants

This device is an absorbent panties fully breathable which must be worn as a normal underwear, providing comfort and freedom of movement. The soft and elastic sides allow the patients to wear it in total comfort. The main body is made of absorbent fluff pulp and superabsorbent polymers, with the innovative Odour stop system.

(Suitable for people with incontinence problems from moderate to severe grade.)



Ref	Ean	Paraph	N.T.N.	Size	Absorb.	Drops	Pcs/Pack	Pcs/Cart.
03JOL8201410	8004007820816	932230067	RIC. 09.30.04.003	S	EXTRA		14	84
03JOL8201420	8004007820823	932230093	RIC. 09.30.04.003	M			14	84
03JOL8201430	8004007820830	932230117	RIC. 09.30.04.003	L			14	84
03JOL8201440	8004007820847	932230129	RIC. 09.30.04.003	XL			14	84
03JOL8301420	8004007830822	933011443	RIC. 09.30.04.003	M	SUPER		14	84
03JOL8301430	8004007830839	933011468	RIC. 09.30.04.003	L			14	84
03JOL8301440	8004007830846	933011470	RIC. 09.30.04.003	XL			14	84

FARMEX AIR, these new aids provide air circulation, by preventing the onset of skin complications.

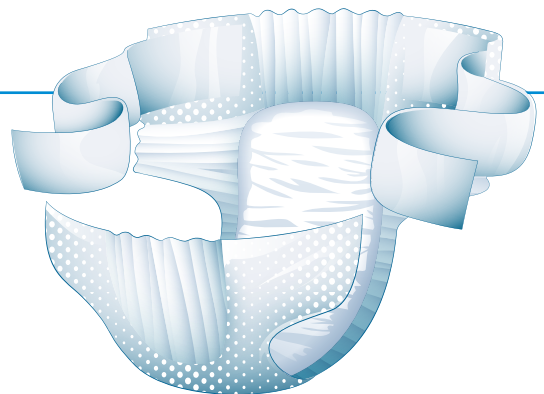
Moreover new products FARMEX AIR ensure superior comfort thanks to their softness and noiseless.



Farmex® Belt

This innovative device is completely breathable. Its fastening system, with Velcro closure, ensures maximum comfort and excellent wearability; the patient can also wear the diaper also individually. Easier and faster to change than any other conventional diapers.

(Ideal for people with moderate to severe incontinence grade.)



Ref	Ean	Paraph	N.T.N.	Size	Absorb.	Drops	Pcs/Pack	Pcs/Cart.
02JOL6122510	8004007070082	939267896	RIC. 09.30.04.009	S	EXTRA		25	75
02JOL6122520	8004007070099	939267959	RIC. 09.30.04.006	M			25	75
02JOL6122530	8004007070105	939268001	RIC. 09.30.04.003	L			25	75

Soft wipes

Extra large and extra soft wipes, ideal for the daily hygiene of delicate and sensitive skin especially when exposed to irritants. They are suitable for the daily hygiene, easy and fast to use in case of mobility and incontinence problems.

They remove impurities and are essential where use of water is limited or no option at all. Gently clean, leaving skin soft and velvety, giving a pleasant sensation of freshness and relief.

Easy to use due to extra large dimensions.

*NO RINSE OFF WITH WATER IS REQUIRED AFTER USE.
MICROWAVE HEATING.*

Soft wipes, particularly suitable for bedridden and changing diapers.

Formulated with Vitamin E (Antioxidant, Physiologic PH)

Chamomile and Cornflower Extract (Rejuvenating, soothing and protecting effect)

Natural Bisabolol added (Refreshing and moisturizing)

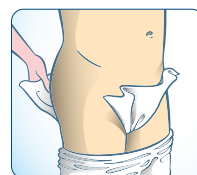


**NO ALCOHOL
HYPOALLERGENIC**

particularly
suitable for



Bedridden



Changing diapers

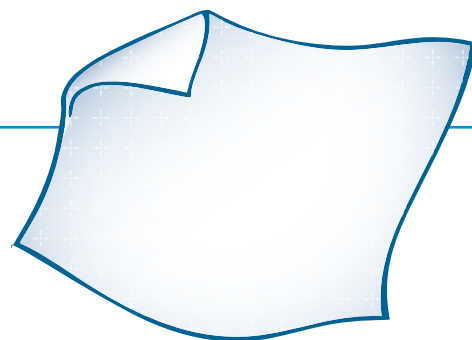
Ref	Ean	Size	Pcs/Pack	Pcs/Cart.
03JOL9100240	8004007910005	20 x 30	24	12 X 24



Fluff Wipes

Made of pure cellulose Fluff wipes are multi-purpose wipes with high absorption. Extremely resistant they can be used both dry and wet. Fluff Wipes, soft and fluffy, gently deterge and dry.

(Wet with warm water, with a small quantity of cleansing lotion or lightly moistened for gentle refreshing.)



Ref	Ean	Size	Pcs/Pack	Pcs/Cart.
03JOL9111000	8004007911002	30 x 40 cm	100	12 X 100

Bibs with pocket

Equipped with a handy pocket and preventing strangulation neck ties. Made of soft polyethylene and a layer of pure absorbent cellulose.

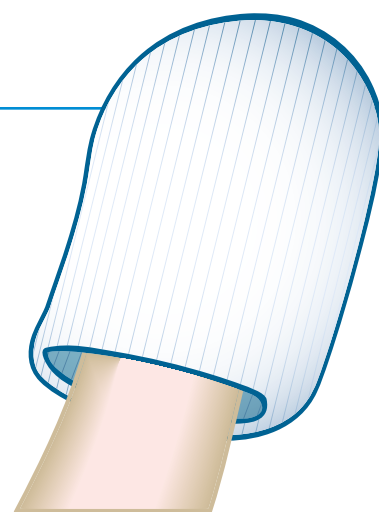


Ref	Ean	Size	Pcs/Pack	Pcs/Cart.
03JOL9121500	8004007912009	48 x 68 cm	150	6 X 150

Wash Gloves

Made of soft synthetic fabric polyester, you can find on the surface a series of thin parallel strips of dry soap with ph neutral, produced according to an industrial processing. Easy to use disposable, it does not irritate the patient's skin but prevents infections that can be caused by usual disposable wash gloves. When just lightly moistened, disposable wash glove activates the detergent soap dry creating a soft and effective foam.

After body washing is possible to remove the excess foam using a multi-purpose fluff wipes.



Ref	Pcs/Pack	Pcs/Cart.
7SVAS9007210	50	20 X 50





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FXS-021/2013-10/Rev.00



MINISTERIO
DE SANIDAD, SERVICIOS SOCIALES
E IGUALDAD



agencia española de
medicamentos y
productos sanitarios

CERTIFICADO CE DE GARANTÍA DE CALIDAD DE LA PRODUCCIÓN
de acuerdo con el Anexo V de la Directiva 93/42/CEE

EC PRODUCTION QUALITY ASSURANCE CERTIFICATE
in accordance with Annex V of Directive 93/42/EEC

PRÓRROGA/EXTENSION — Fecha inicial/ Initial date: 18-05-1998

Fecha de prórrogas anteriores: 16-05-2003, 14-05-2008, 17-02-2009

Certificado n.º/Certificate no	Fecha de validez/Date of validity	ON n.º/NB no
98 05 0092 CP	Desde/From: 17-02-2014 Hasta/To: 16-02-2019	0318

A favor de /In favour of:

Fabricante/Manufacturer:

Nombre/Name: IBERHOSPITEX, S.A.

Dirección/Address: Avda. Catalunya, 4; 08185 – Lliça de Vall (Barcelona) ESPAÑA

Representante autorizado ante la UE/Authorized EU representative:

Nombre/Name: Idem

Dirección/Address: Idem

Para el producto/For the product:

Categoría/Category: Productos de un solo uso / Single use devices

Grupo genérico/Generic group: Especificados en Anexos de este Certificado/Specified in Annexes to this Certificate.

Tipo/Type: Especificados en Anexos de este Certificado/Specified in Annexes to this Certificate.

Elaborado en/In the facilities:

IBERHOSPITEX, S.A

Avda. Catalunya, 4; 08185 – Lliça de Vall (Barcelona) ESPAÑA

Este certificado debe ir acompañado por/This certificate must be accompanied by:

- ☐ Certificado de examen CE de tipo (anexo III)/EC Type examination certificate (annex III)
☒ Declaración CE de conformidad (anexo VII)/EC declaration of conformity (annex VII)

Este certificado es consecuencia de la auditoría del sistema de garantía de calidad de la producción y del examen de la documentación técnica contenida en el expediente n.º 97 10 0062, y garantiza que los productos descritos cumplen los requisitos de la Directiva.

This certificate is issued on the production quality assurance system audit, and the examination of the technical documentation contained in dossier no. 97 10 0062, and guarantees that the described products fulfils the requirements of the Directive.

Madrid, 17 de febrero de 2014

 **agencia española de
medicamentos y
productos sanitarios**
P.A. art. 14.4 del Estatuto de la AEMPS
(R.D. 1275/2011, de 16 de septiembre)

La Directora  **agencia española de
medicamentos y
productos sanitarios**
ORGANISMO NOTIFICADO
0318

Fco. Javier Muñoz Aizpuru

CORREO ELECTRÓNICO

on0318@aemps.es

ORGANISMO NOTIFICADO 0318

Página 1 de 1

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28022 MADRID
TEL: 902101322
FAX: 91 822 52 89



ANEXO N° I/ANNEX NO: I

CERTIFICADO CE DE GARANTÍA DE CALIDAD DE LA PRODUCCIÓN
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98 05 0092 CP	Desde/From: 17-02-2014 Hasta/To: 16-02-2019	0318

A favor de /In favour of:

Fabricante/Manufacturer:

Nombre/Name: IBERHOSPITEX, S.A.

Dirección/Address: Avda. Catalunya, 4; 08185 – Llíça de Vall (Barcelona) ESPAÑA

Representante autorizado ante la UE/Authorized EU representative:

Nombre/Name: Idem

Dirección/Address: Idem

Productos/Product: 17

Variantes/Variants: 56

Tipo de producto / Device type: Productos para quirófanos o salas de quemados. Apósitos autoadhesivos. Fundas cubreinstrumentos /Operating room devices. Adhesive dressing. Instruments covers

Clasificación/Classification: I estéril / I sterile

1. Productos para quirófanos o salas de quemados/ Operating room devices (GMDN 35091)

1.1 Vestuario y prendas de protección de tela sin tejer/ Operating room devices

1.1.a. Bata de protección estéril/ Sterile protection gown

1.1.b Bata de protección impermeable estéril /Sterile plastified protection gown

1.1.c. Bata quirúrgica reforzada estéril de polipropileno SMMS/ Sterile SMMS polypropylene reinforced surgical gown

Tallas/ Sizes: M, L y XL

1.1.d Bata quirúrgica no reforzada estéril de polipropileno SMMS/ Sterile SMMS non reinforced polypropylene surgical gown

Tallas/ Sizes: M, L y XL

1.2 Fundas cubreinstrumentos de Ø / Instruments covers to Ø: 100 cm y 123 cm (GMDN 45021)

ANEXO Nº/ANNEX NO: I
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Certificado nº/Certificate no	Fecha de validez/Date of validity	ON nº/NB no
98 05 0092 CP	Desde/From: 17-02-2014 Hasta/To: 18-02-2019	0318

2. Conjuntos quirúrgicos para diálisis y curas / Dialysis and Healing surgical sets
(GMDN 32142)

2.1 Conjuntos para diálisis/ Dialysis surgical sets:

- 1 Guantes de látex de examen/ Latex examination gloves: 6: 6 ½, 7: 7 ½**
- 1 Talla tisú absorbente / Absorbent surgical drape**
- 4 Tallas absorbentes / Absorbent towels**

2.2 Conjuntos para curas/ Healing surgical sets:

- 1 Guantes de látex de examen/ Latex examination gloves: 6: 6 ½, 7: 7 ½**
- 1 Talla tisú absorbente / Absorbent surgical drape**
- 4 Tallas absorbentes / Absorbent towels**
- 1 Pinzas de disección / Dissection tweezers**
- 1 Pinzas Kocher / Kocher tweezers**

3. Apósitos autoadhesivos /Self-adhesive dressings (GMDN 46854)

3.1 OPER FILM Membrana de poliuretano autoadhesiva/ Polyurethane self adhesive membrane.

Tamaños/Sizes: 60 x 40 cm, 40 x 40 cm, 30 x 40 cm, 30 x 27 cm, 30 x 16 cm, 15 x 10 cm, 10 x 7.5 cm, 60 x 80 cm y 6.5 x 7.5 cm.

3.2- OPER DRES Apósito autoadhesivo con adhesivo acrílico y compresa central de viscosa-poliéster / Acrylic self-adhesive dressing with viscose-polyester central swab

Tamaños/Sizes: 7.2 x 5 cm, 9 x 5 cm, 9 x 10 cm, 9 x 15 cm, 9 x 20 cm, 9 x 25 cm, 9 x 30 cm y 9 x 35 cm.



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EC PRODUCTION QUALITY ASSURANCE CERTIFICATE
in accordance with Annex V of Directive 93/42/EEC

PRÓRROGA/EXTENSION — Fecha inicial/ Initial date: 18-05-1998
Fecha de prórrogas anteriores: 16-05-2003, 14-05-2008, 17-02-2009

Certificado nº/Certificate no	Fecha de validez/Date of validity	ON nº/NB no
98 05 0092 CP	Desde/From: 17-02-2014 Hasta/To: 18-02-2019	0318

3.3- OPER CAT Bolsa apósito autoadhesivo acrílico de viscosa-poliéster/ Acrylic self-adhesive dressing pouch viscose-polyester.

Tamaños/Sizes: 8 x 7.5 cm, 16 x 5 cm.

3.4- OPER DRES FILM. Apósito quirúrgico autoadhesivo de poliuretano con adhesivo acrílico y compresa central de viscosa (90% viscosa y 10% polipropileno) / Polyurethane self-adhesive surgical dressing with acrylic and viscose central swab (90% viscose and 10% polypropylene)

Tamaños/Sizes: 7.2 x 5 cm, 9 x 5 cm, 9 x 10 cm, 9 x 15 cm, 9 x 20 cm, 9 x 25 cm, 9 x 30 cm y 9 x 35 cm.

3.5- OPER EASY Apósito autoadhesivo con adhesivo acrílico de poliuretano/ Polyurethane acrylic self-adhesive dressing.

Tamaños/Sizes: : 7.2 x 5 cm, 9 x 12 cm y 9 x 15 cm.

3.6- OPER STRIP Tira adhesiva de suturas cutáneas/ Skin sutures adhesive strip.

Tamaños/Sizes: 3 x 75 mm, 6 x 38 mm, 6 x 75 mm, 6 x 100 mm, 12 x 100 mm y 25 x 125 mm.

3.7- OPER EASY I.V Apósito transparente con adhesivo acrílico de poliuretano para fijación de cánulas/ Polyurethane acrylic self-adhesive transparent dressing for cannula fixation.

Tamaños/Sizes:: 7.2 x 5 cm.

3.8- OPER EASY I.V STRIP Apósito transparente con adhesivo acrílico de poliuretano para fijación de cánulas con tiras de refuerzo / Polyurethane acrylic self-adhesive transparent dressing for cannula fixation with securing strips.

Tamaños/Sizes: : 9 x 7 cm.

ORGANISMO NOTIFICADO 0318



ANEXO Nº/ANNEX NO: I
CERTIFICADO CE DE GARANTÍA DE CALIDAD DE LA PRODUCCIÓN
de acuerdo con el Anexo V de la Directiva 93/42/CEE

EC PRODUCTION QUALITY ASSURANCE CERTIFICATE
in accordance with Annex V of Directive 93/42/EEC

PRÓRROGA/EXTENSION — Fecha inicial/ Initial date: 18-05-1998
Fecha de prórrogas anteriores: 16-05-2003, 14-05-2008, 17-02-2009

Certificado nº/Certificate no	Fecha de validez/Date of validity	ON nº/NB no
98 05 0092 CP	Desde/From: 17-02-2014 Hasta/To: 18-02-2019	0318

3.9- OPER FILM SURGICAL Apósito autoadhesivo con adhesivo acrílico de poliuretano transparente/ *Polyurethane acrylic self-adhesive transparent dressing*
Tamaños/Sizes: 24 x 16 cm, 24 x 27 cm, 24 x 40 m, 34 x 40 cm, 34 x 60 cm y 53 x 80 cm.

Este certificado ampara todas las marcas de estos productos incluidas por el fabricante en su declaración de conformidad.

This certificate covers all trademarks of these products included by the manufacturer in his declaration of conformity.

Madrid, 17 de febrero de 2014

La Directora

 **agencia española de
medicamentos y
productos sanitarios**
P.A. art. 14.4 del Estatuto de la AEMPS
(R.D. 1275/2011, de 16 de septiembre)

 **agencia española de
medicamentos y
productos sanitarios**
ORGANISMO NOTIFICADO
0318

Fco. Javier Muñoz Aizpuru

ORGANISMO NOTIFICADO 0318

Traducere din limba engleză

CERTIFICAT DE ASIGURARE A CALITĂȚII PRODUCȚIEI CE
în conformitate cu anexa V a Directivei 93/42 CEE

Data emiterii inițiale: 18-05-1998

Prelungiri: 16-05-2003, 14-05-2008, 17-02-2009

Certificat nr.	Data valabilității	NR
98 05 0092 CP	De la: 17-02-2014 Până la: 16-02-2019	0318

Emis pentru:

Producător:

Nume: IBERHOSPITEX, S.A.

Adresa: Avda. Catalunya, 4; 08185 - Llica de Vail (Barcelona) SPANIA

Reprezentant UE autorizat:

Nume: Idem

Adresa: Idem

Pentru produsul:

Categorie: Dispozitive de unică folosință

Grup generic: Specificat în anexele la prezentul Certificat.

Tip: Specificat în anexele la prezentul Certificat.

În centrele de producție:

IBERHOSPITEX, S.A

Avda. Catalunya, 4; 08185 - Llica de Vail (Barcelona) SPANIA

Prezentul Certificat trebuie să fie însoțit de:

- Certificat de examinare tip CE (anexa III)
- Declarație de conformitate CE (anexa VII)

Prezentul Certificat este emis în urma auditului sistemului de asigurare a calității producției și pe baza examinării documentației tehnice din dosarul nr. 97 10 0062, și garantează faptul că produsele descrise îndeplinesc cerințele Directivei.

Madrid, 17 februarie 2014,

Director

Fco. Javier Munoz Aizpuru

Semnătură indescifrabilă

Ștampila Ministerului sănătății din Spania

Ștampila Agenției spaniole pentru medicamente și produse sanitare

CORREO ELECTRONICO
on0318@aemps.es

ORGANISM NOTIFICAT 0318

Pagina 1 din 1

CI CAMPEZO, 1 – EDIFICIO 8
28022 MADRID
28022 MADRID
TEL: 902101322
FAX: 91 822 52 89



ANEXA NR. I
CERTIFICAT DE ASIGURARE A CALITĂȚII PRODUCȚIEI CE
în conformitate cu anexa V a Directivei 93/42 CEE
Data emiterii inițiale: 18-05-1998
Prelungiri: 16-05-2003, 14-05-2008, 17-02-2009



Certificat nr.	Data valabilității	NR
98 05 0092 CP	De la: 17-02-2014 Până la: 16-02-2019	0318

Emis pentru:

Producător:

Nume: IBERHOSPITEX, S.A.

Adresa: Avda. Catalunya, 4; 08185 - Llica de Vail (Barcelona) SPANIA

Reprezentant UE autorizati:

Nume: Idem

Adresa: Idem

Produs: 17

Variante: 56

Tip dispozitiv: Dispozitive pentru sala de operație. Pansamente adezive. Huse pentru instrumente

Clasificare: I steril

1. Dispozitive pentru sala de operații (GMDN 35091)

1.1 Dispozitive pentru sala de operații

1.1.a. Halat de protecție steril

1.1.b Halat de protecție plastifiat steril

1.1.c. Halat chirurgical îngroșat polipropilenă SMMS steril. Dimensiuni: M, L și XL

1.1.d Halat chirurgical neîngroșat polipropilenă SMMS steril. Dimensiuni: M, L și XL

1.2 Huse instrumente Ø: 100 cm și 123 cm (GMDN 45021)

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ANEXA NR. I
CERTIFICAT DE ASIGURARE A CALITĂȚII PRODUCȚIEI CE
în conformitate cu anexa V a Directivei 93/42 CEE
Data emiterii inițiale: 18-05-1998
Prelungiri: 16-05-2003, 14-05-2008, 17-02-2009

Certificat nr.	Data valabilității	NR
98 05 0092 CP	De la: 17-02-2014 Până la: 16-02-2019	0318

2. Seturi chirurgicale de tratament și dializă (GMDN 32142)

2.1 Seturi chirurgicale de dializă:

1 Mănuși de examinare din latex: 6, 6 1/2, 7, 7 1/2

1 Câmp operator absorbant

4 Prosoape absorbante

2.2 Seturi chirurgicale de tratament:

1 Mănuși de examinare din latex: 6, 6 1/2, 7, 7 1/2

1 Câmp operator absorbant

4 Prosoape absorbante

1 Pensete de disecție

1 Pensete Kocher

3. Pansamente autoadezive (GMDN 46854)

3.1 OPER FILM Membrană autoadezivă din poliuretan.

Dimensiuni: 60 x 40 cm, 40 x 40 cm, 30 x 40 cm, 30 x 27 cm, 30 x 16 cm, 15 x 10 cm, 10 x 7.5 cm, 60 x 80 cm și 6.5 x 7.5 cm.

3.2- OPER DRES Pansament auto-adeziv din acrilic cu tampon central din poliester - vâscoză

Dimensiuni: 1.2 x 5 cm, 9x5 cm, 9x10 cm, 9 x 15 cm, 9 x 20 cm, 9 x 25 cm, 9 x 30 cm y 9 x 35 cm.

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ORGANISM NOTIFICAT 0318
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CI CAMPEZO, 1 – EDIFICIO 8
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ANEXA NR. I
CERTIFICAT DE ASIGURARE A CALITĂȚII PRODUCȚIEI CE
în conformitate cu anexa V a Directivei 93/42 CEE

Data emiterii inițiale: 18-05-1998

Prelungiri: 16-05-2003, 14-05-2008, 17-02-2009

Certificat nr.	Data valabilității	NR
98 05 0092 CP	De la: 17-02-2014 Până la: 16-02-2019	0318

3.3- OPER CAT Pansament auto-adeziv acrilic pungă vâscoză - poliester.

Dimensiuni: 8 x 7.5 cm, 16 x 5 cm.

3.4- OPER DRES FILM Pansament chirurgical auto-adeziv poliuretan cu tampon central din viscoză și acrilic (90% viscoză și 10% polipropilenă)

Dimensiuni: 7.2 x 5 cm, 9x5 cm, 9 x 10 cm, 9x15 cm, 9 x 20 cm, 9 x 25 cm, 9 x 30 cm y 9 x 35 cm.

3.5- OPER EASY Pansament auto-adeziv acrilic poliuretan.

Dimensiuni : 7.2 x 5 cm, 9 x 12 cm și 9 x 15 cm.

3.6- OPER STRIP Bandă adezivă pentru suturi cutanate.

Dimensiuni: 3 x 75 mm, 6 x 38 mm, 6 x 75 mm, 6 x 100 mm, 12 x 100 mm și 25 x 125 mm.

3.7- OPER EASY I.V. Pansament transparent auto-adeziv din acrilic poliuretan pentru fixarea canulei

Dimensiuni: 7.2 x 5 cm.

3.8- OPER EASY I.V. STRIP Pansament transparent auto-adeziv din acrilic poliuretan pentru fixarea canulei cu benzi de fixare. *Dimensiuni: : 9 x 7 cm.*

Organism notificat 0318

Pagina 3 din 4

MINISTERIO DE SANIDAD,
SERVICIO SOCIALES
E IGUALDAD
Agencia Espanola de Medicamentos
y Productos Sanitarios





ANEXA NR. I
CERTIFICAT DE ASIGURARE A CALITĂȚII PRODUCȚIEI CE
în conformitate cu anexa V a Directivei 93/42 CEE
Data emiterii inițiale: 18-05-1998
Prelungiri: 16-05-2003, 14-05-2008, 17-02-2009

Certificat nr.	Data valabilității	NR
98 05 0092 CP	De la: 17-02-2014 Până la: 16-02-2019	0318

3.9- OPER FILM SURGICAL Pansament transparent auto-adeziv din acrilic poliuretan
Dimensiuni: 24 x 16 cm, 24 x 27 cm, 24 x 40 m, 34 x 40 cm, 34 x 60 cm și 53 x 80 cm.

Prezentul certificat acoperă toate mărci comerciale produselor incluse de producător în declarația de conformitate.

Madrid, 17 februarie 2014,

Director
Fco. Javier Munoz Aizpuru

Semnătură indescifrabilă

Stampila Ministerului sănătății din Spania

Stampila Agenției spaniole pentru medicamente și produse sanitare

Organism notificat 0318

Pagina 4 din 4

MINISTERIO DE SANIDAD,
SERVICIO SOCIALES
E IGUALDAD
Agencia Espanola de Medicamentos
y Productos Sanitarios



Ministerul Sănătății din Spania și Agenția spaniolă pentru medicamente și produse sanitare și a
fost prezentat mie în întregime.

Traducerea înscrisului prezentat are un număr de 5 pagini și a fost efectuată potrivit cererii scrise
înregistrate cu nr. 57 / 04.08.2014, păstrate în arhiva subsemnatei.

S-a încasat onorariul de 80 lei, cu Factura nr. 410 / 04.08.2014.

INTERPRET ȘI TRADUCĂTOR AUTORIZAT

Olaru Ruxandra, www.trada.ro, office@trada.ro, telefon: 0729.22.6789



UNE-EN ISO 13485:2013 CERTIFICADO DE PRÓRROGA
UNE-EN ISO 13485:2013 EXTENSION CERTIFICATE

Productos Sanitarios: Sistemas de Gestión de Calidad – Requisitos para fines reglamentarios.
Medical devices – Quality management systems - Requirements for regulatory purposes.

PRÓRROGA/EXTENSION — Fecha inicial/ Initial date: 16-05-2003

Fechas de prórroga anteriores/Previous extension: 9-06-2004, 17-02-2009, 17-02-2014

Fecha de validez/This Certificate is valid until: 17.02.2019

Certificado nº/Certificate no: 2014 02 0041 EN

Empresa/ Company

IBERHOSPITEX, S.A

Nombre y dirección/name and address:

Avda. Catalunya, 4; 08185 – Llíça de Vall (Barcelona) ESPAÑA

Objeto de la Certificación/Applicable to:

Diseño y desarrollo, y producción de productos sanitarios/ Design and manufacture of medical devices

Ámbito tecnológico/Technological scope:

Especificado en Anexo a este Certificado/Specified in Annex to this Certificate.

La Agencia Española de Medicamentos y Productos Sanitarios, certifica que la empresa reseñada más arriba tiene establecido y aplica un sistema de gestión de de calidad de conformidad con la norma UNE-EN ISO 13485:2013 (EN ISO 13485:2012 e ISO 13485:2003).

The Agencia Española de Medicamentos y Productos Sanitarios, certifies herewith that the company named above has established and applies a quality management system according to the standard UNE-EN ISO 13485:2013 (EN ISO 13485:2012 and ISO 13485:2003).

Madrid, 17 de febrero de 2017

**LA DIRECTORA DE LA AGENCIA ESPAÑOLA DE
MEDICAMENTOS Y PRODUCTOS SANITARIOS**



agencia española de
medicamentos
y productos sanitarios
ORGANISMO NOTIFICADO
0318

Belén Crespo Sánchez-Eznarriaga

Anexo al certificado nº 2014 02 0041 EN /annex to certificate no: 2014 02 0041 EN
Fecha /date: 17 de febrero de 2017

Ámbito tecnológico/technological scope:

PRODUCTOS SANITARIOS NO ACTIVOS/ NON-ACTIVE MEDICAL DEVICES :

**PRODUCTOS SANITARIOS NO ACTIVOS, NO IMPLANTABLES, EN GENERAL/
GENERAL NON ACTIVE, NON-IMPLANTABLE MEDICAL DEVICES:**

-Productos no activos para anestesia y respiración, emergencia y cuidado intensivo/ *Non-active devices for anaesthesia, respiration, emergency and intensive care*

-Dispositivos de acceso percutáneo, para tratamiento de enfermedades vasculares/*Percutaneous access device for treatment of vascular disease*

IMPLANTES NO ACTIVOS/ NON-ACTIVE IMPLANTS :

-Implantes cardiovasculares no activos /*Non-active cardiovascular implants*

PRODUCTOS PARA CUIDADO DE HERIDAS/ DEVICES FOR WOUND CARE:

-Vendajes y apósitos para heridas/ *Bandages and wound dressings*

**OTROS PRODUCTOS SANITARIOS NO ACTIVOS DIFERENTES DE LOS
ESPECIFICADOS ARRIBA**

-Equipamiento y vestimenta destinados a la preservación de la contaminación del paciente en entornos médico-quirúrgicos/*Equipment and clothing for the preservation of patient contamination in medical-surgery settings*

**PRODUCTOS SANITARIOS ACTIVOS NO IMPLANTABLES/ ACTIVE (NON-
IMPLANTABLE) MEDICAL DEVICES :**

**PRODUCTOS SANITARIOS ACTIVOS, EN GENERAL/ GENERAL ACTIVE MEDICAL
DEVICES :**

OTROS PRODUCTOS SANITARIOS ACTIVOS NO IMPLANTABLES:

-Productos para drenaje y succión//*Drain and suction devices*

**PRODUCTOS SANITARIOS QUE INCORPORAN DETERMINADAS
TECNOLOGÍAS/MEDICAL DEVIDES INCORPORATING ESPECIFIC SUBSTANCES**

**-PRODUCTOS SANITARIOS QUE INCORPORAN SUSTANCIAS MEDICINALES/
MEDICAL DEVICES INCORPORATING MEDICINAL SUBSTANCES**

MINISTERUL SANATATII, SERVICIILOR SOCIALE SI EGALITATII
AGENTIA SPANIOLA PENTRU MEDICAMENTE SI PRODUSE SANITARE

CERTIFICAT DE PRELUNGIRE UNE-EN ISO 13485 :2013
Dispozitive medicale – sisteme de gestionare a calitatii – cerinte de reglementare

PRELUNGIRE – Data initiala : 16-05-2003
Prelungiri precedente : 9-06-2004, 17-02-2009, 17-02-2014
Prezentul certificat expira la data de : 17.02.2019
Certificat nr. : 2014 02 0041 EN

Compania: IBEROHOSPITEX, S.A.
Denumirea si adresa: Avda. Catalunya, 4; 08185 Llica de Vall (Barcelona) SPANIA
Obiectul certificatului: Proiectarea si fabricatia dispozitivelor medicale
Scopul tehnologic: Specificat in Anexa prezentului Certificat.

Agentia spaniola pentru medicamente si produse sanitare certifica, prin prezentul, faptul ca societatea comerciala mentionata mai sus a stabilit si aplicat un sistem de gestionare a calitatii conform standardului UNE-EN ISO 13485:2013 (EN ISO 13485:2012 si ISO 13485:2003).

Madrid, 17 Februarie 2017
DIRECTOAREA AGENTIEI SPANIOLE PENTRU MEDICAMENTE SI PRODUSE SANITARE
Belen Crespo Sanchez-Eznarriaga
(Semnatura indescifrabila si stampila Agentiei)

REDACTAT ELECTRONIC CERTIFICAT 13485 C/CAMPEZO, 1 – CLADIREA 8
on0318@aemps.es Pagina 1 din 2 28022 MADRID
Tel.: 902101322
Fax: 91 822 52 89



Data: 17 Februarie 2017

Scop tehnologic:

DISPOZITIVE MEDICALE INACTIVE:

DISPOZITIVE MEDICALE GENERALE, INACTIVE, NEIMPLANTABILE:

- Dispozitive inactive pentru anestezie, respiratie, asistenta de urgenta si terapie intensiva
- Dispozitive de acces percutanat pentru tratamentul afectiunilor vasculare

IMPLANTURI INACTIVE:

- Implanturi cardiovasculare inactive

PRODUSE DE ÎNGRIJIRE A LEZIUNILOR:

- Bandaje si pansamente pentru leziuni

DISPOZITIVE MEDICALE INACTIVE, ALTELE DECAT CELE ENUMERATE ANTERIOR:

- Echipamente si imbracaminte pentru prevenirea contaminarii pacientilor din unitatile medico-chirurgicale

DISPOZITIVE MEDICALE ACTIVE, NEIMPLANTABILE:

DISPOZITIVE MEDICALE ACTIVE, DE UZ GENERAL:

ALTE DISPOZITIVE MEDICALE NEIMPLANTABILE:

- Dispozitive pentru drenaj si aspiratie

DISPOZITIVE MEDICALE CARE INCORPOREAZA SUBSTANTE SPECIFICE:

- DISPOZITIVE MEDICALE CARE INCORPOREAZA SUBSTANTE MEDICINALE

CERTIFICAT 13485

Pagina 2 din 2

MINISTERUL SANATATII,
SERVICIILOR SOCIALE
SI EGALITATII
AGENTIA SPANIOLA
PENTRU MEDICAMENTE
SI PRODUSE SANITARE

Subsemnata **MUSUROIA MIRELA**, traducator autorizat de Ministerul Justitiei, certific exactitatea acestei traducerii cu textul înscrisului original în limba engleza, ce a fost vizat de mine.

Traducător autorizat
Nr. 2769/2015



Oper tape

Surgical tape



Hospital Care

A safe and comfortable barrier

Optimal fixation. High perspiration. Elasticity and comfort. Hypoallergenic adhesive.



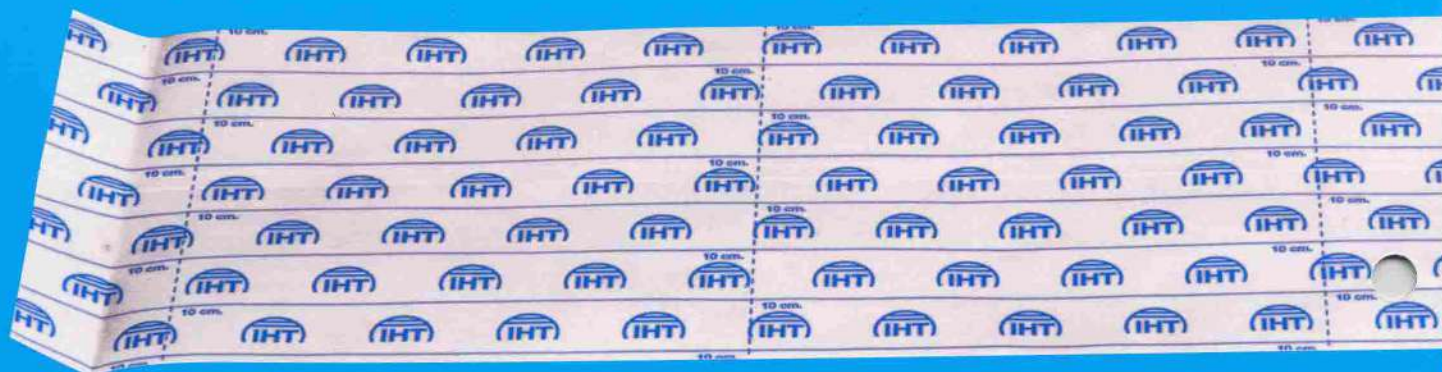
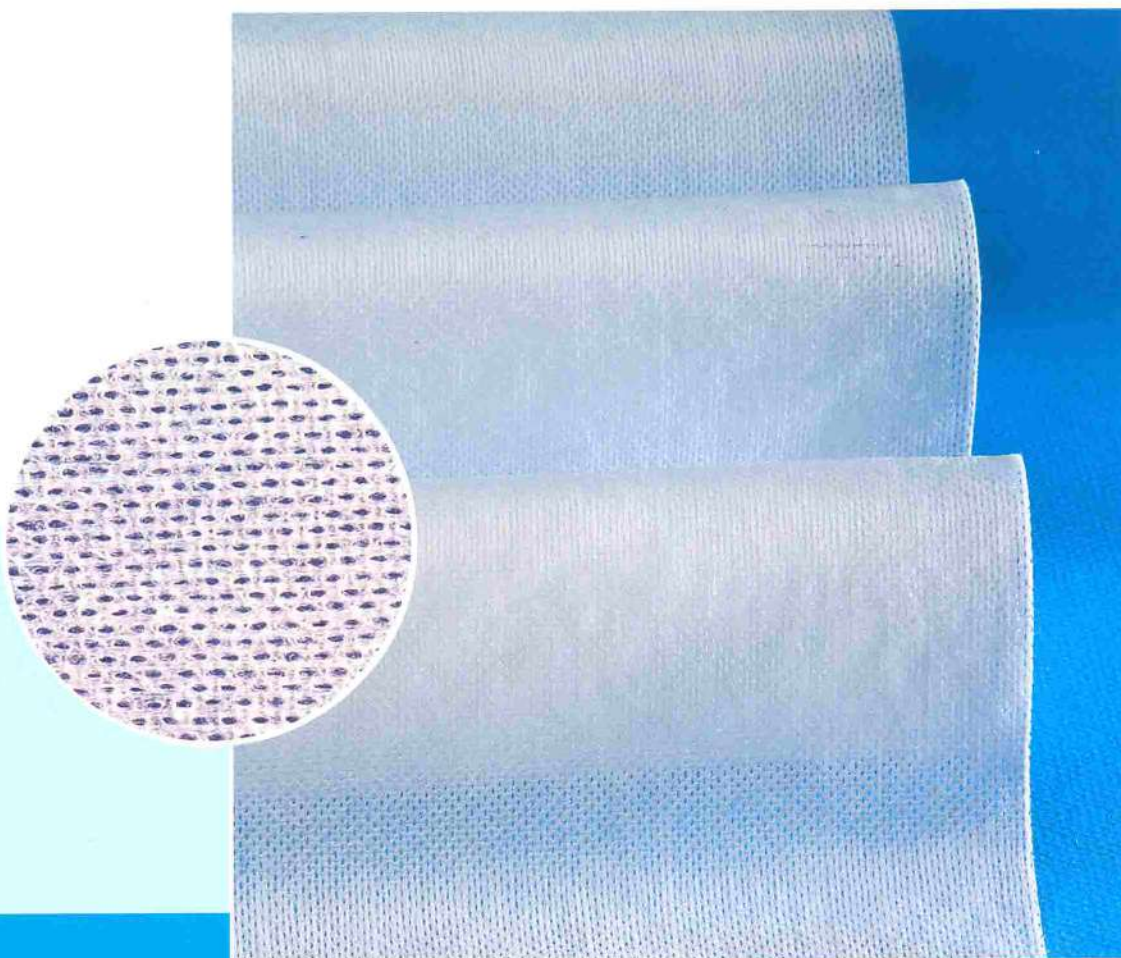


Oper tape

Surgical tape

Extensible and really perspirant

Oper tape system for fixing compresses is an adaptable, extensible, highly porous, non woven material covered by a hypoallergenic adhesive. The adhesive area is protected by precut silicon paper which allows quick and easy application.





Transversal extensibility of the non woven material

Being a transversally extensible strip **Oper tape** can be used on articulations without risk of loosening.

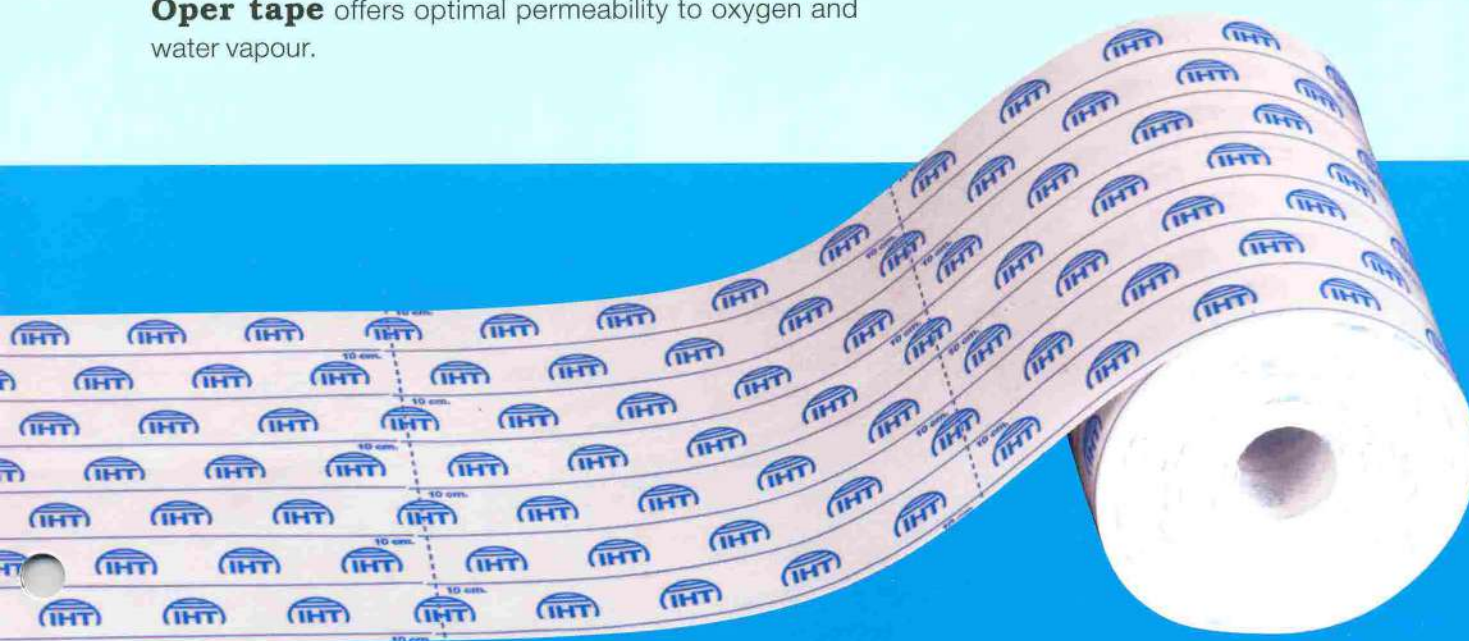


Different size presentations

The extensive range of sizes of **Oper tape** allows for the covering of any size of pad in one application, thus facilitating the work of hospital staff.

Permeable to oxygen and water vapour

Thanks to the high porosity of the non woven material together with the ultimate production process of adhesive fixing, **Oper tape** offers optimal permeability to oxygen and water vapour.



Oper tape

Surgical tape

Maximum adaptability and comfort

Autoadhesive material (Non woven 100% polyester, acrylic copolymer adhesive, silicon paper)

Presentation				
Reference	Dimensions	Units per box	Boxes per carton	Sales unit
0032210	2,5 cm x 10m	2	180	360
0032220	5 cm x 10m	1	180	180
0032230	10 cm x 10m	1	90	90
0032240	15 cm x 10m	1	60	60
0032250	20 cm x 10m	1	47	47
0032260	30 cm x 10m	1	30	30

00051101 - rev. 2011/09/20

