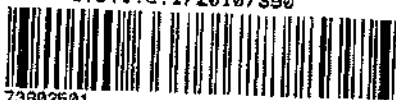


Ministero della Salute

DGFDH

0029413-P-28/07/2010

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



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

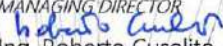
This Certificate should be made public only in integral form, complete Annex 1

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 ISR 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° 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.

Pagina 1 di 1

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.

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

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° 132B
SGA N° 020D ISP N° 075E
PRS N° 097C

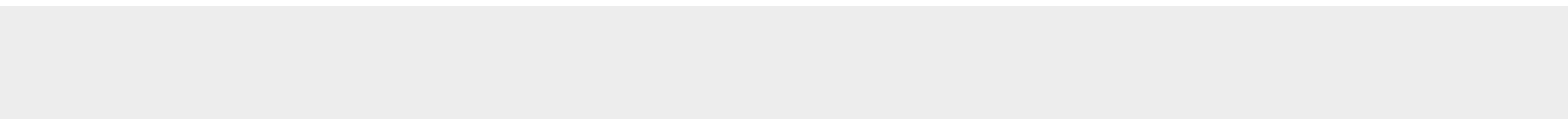
Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements



FARMEX



Adult incontinence devices





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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

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Fluff wipes 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

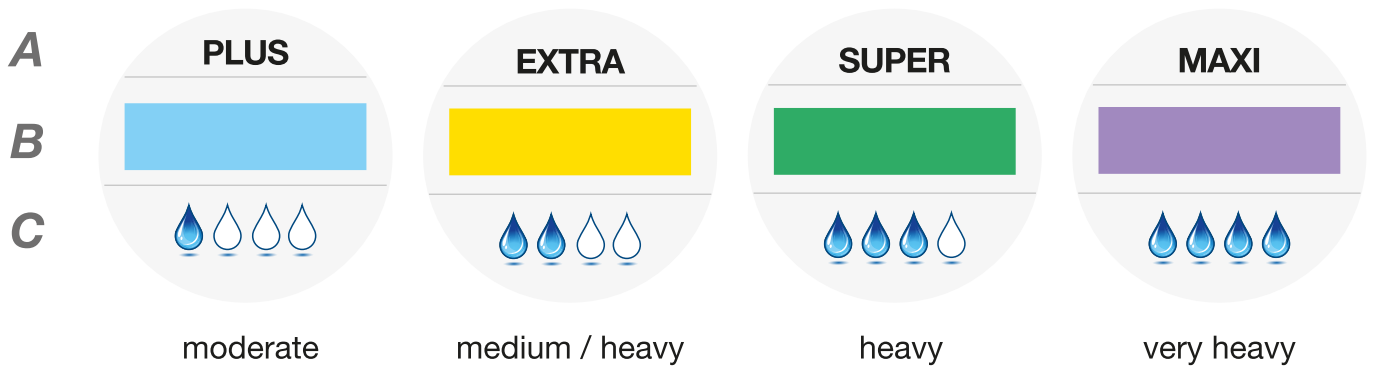
Farmex Incontinence Devices



(Degrees of incontinence)

Absorbency level

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



Sample pack



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.

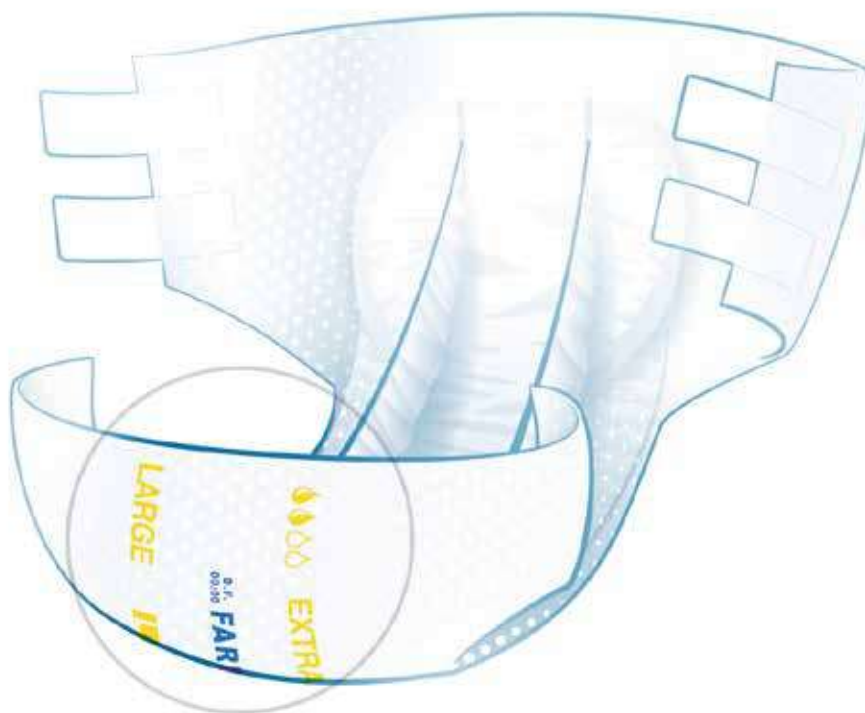
Our four different absorbency levels are identifiable by the color code and drops number printed.

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.

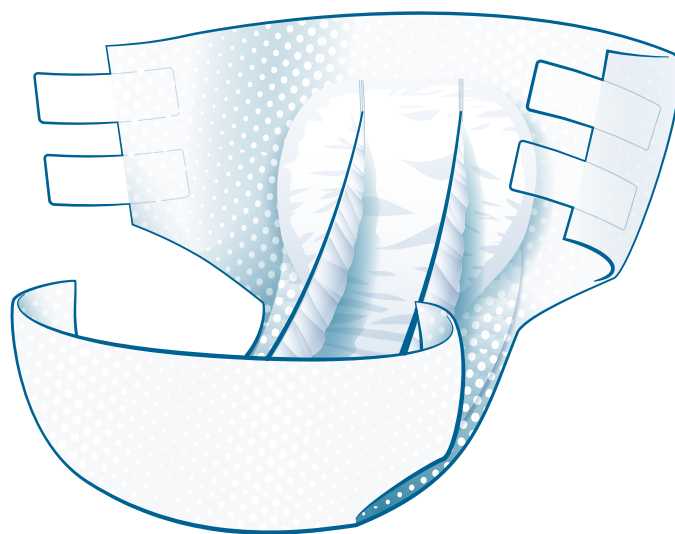


HYPOALLERGENIC

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.)

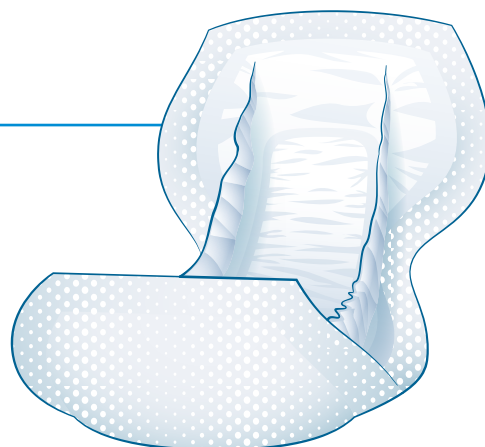


Ref	Ean	Paraph	N.T.N.	Size	Absorb.	Drops	Pcs/Pack	Pcs/Cart.
03JOL3103020	8004007310324	931436808	RIC. 09.30.04.006	M	PLUS		30	90
03JOL3103030	8004007310331	931436834	RIC. 09.30.04.003	L			30	90
03JOL3201510	8004007320019	931436846	09.30.04.009	S	EXTRA		15	90
03JOL3203020	8004007320323	931436911	09.30.04.006	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

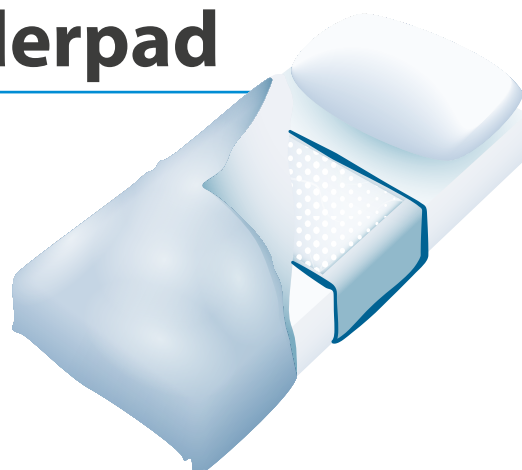
This device is suitable for protection and care of people with moderate incontinence problems, its shape is rectangular with or without barrier to the liquids. Through the use of plastic or elastic panties, this device ensures optimum practical use. The external support is made of soft, non-toxic and 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	3	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	3	30	150	
03JOL4103010	8004007410338	931437127	09.30.04.021	without barrier			30	150	

Farmex® Absorbent Underpad



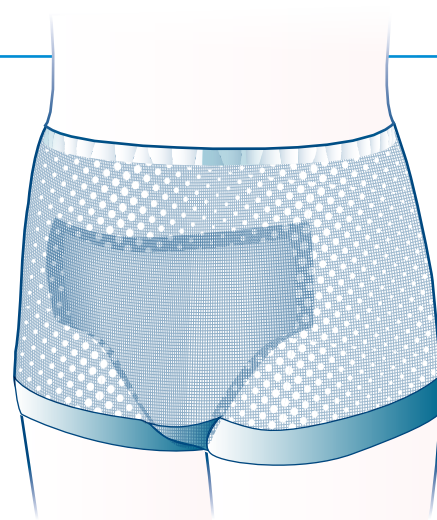
The device is manufactured for all the cases of urinary and fecal incontinence for bedridden patients. It is not wearable, this device may be positioned between the patient and the bed surface in order to ensure the health of people. The external side is made of soft, non-toxic and waterproof polyethylene. 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.

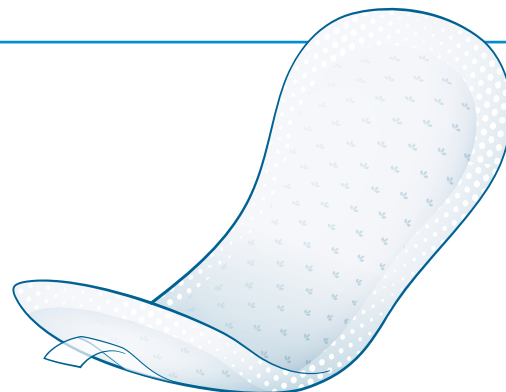


Ref	Ean	Paraph	N.T.N.	Size	Pcs/Pack	Pcs/Cart.
03JOL9600310	8004007960017	932230131	09.30.09.009	SMALL	30 x 3	90
03JOL9600320	8004007960024	932230143	09.30.09.006	MEDIUM	30 x 3	90
03JOL9600330	8004007960031	932230156	09.30.09.003	LARGE	30 x 3	90
03JOL9600340	8004007960048	932230168	RIC. 09.30.09.003	EXTRALARGE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

FARMEX air dermo

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.

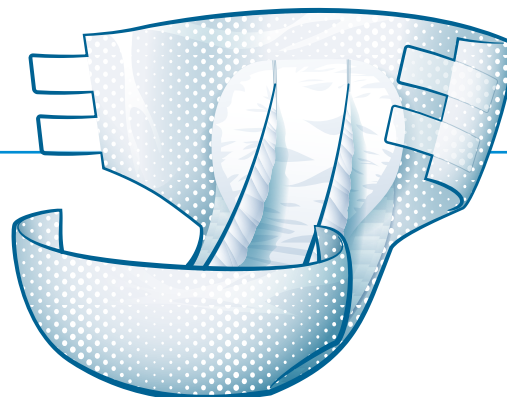
Combination between breathable backsheet and the emollient lotion guarantees to AIR DERMO products an efficient derma-protection system to avoid skin irritation.



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.)



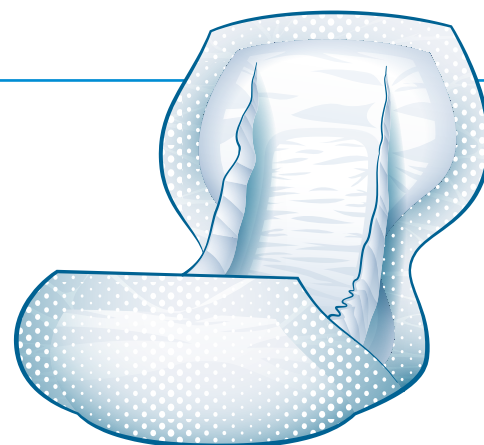
Ref	Ean	Paraph	N.T.N.	Size	Absorb.	Drops	Pcs/Pack	Pcs/Cart.
03JOL3211510	8004007321016	932229901	09.30.04.009	S	EXTRA		15	90
03JOL3213020	8004007321320	932229913	09.30.04.006	M			30	90
03JOL3213030	8004007321337	932229925	09.30.04.003	L			30	90
03JOL3213040	8004007321344	932229937	RIC. 09.30.04.003	XL			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.)

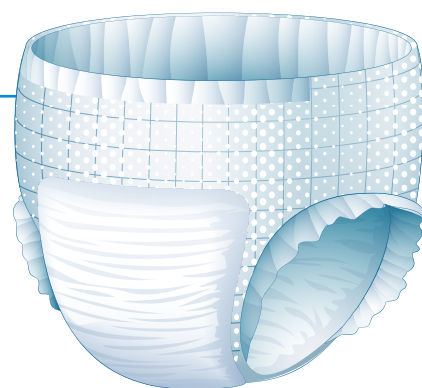


Ref	Ean	Paraph	N.T.N.	Absorb.	Drops	Pcs/Pack	Pcs/Cart.
03JOL2112000	8004007211201	932230004	09.30.04.018	PLUS		20	80
03JOL2212000	8004007221200	932230016	09.30.04.015	EXTRA		20	80
03JOL2312000	8004007231209	932230030	09.30.04.012	SUPER		20	80
03JOL2412000	8004007241208	932230042	RIC. 09.30.04.012	MAXI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

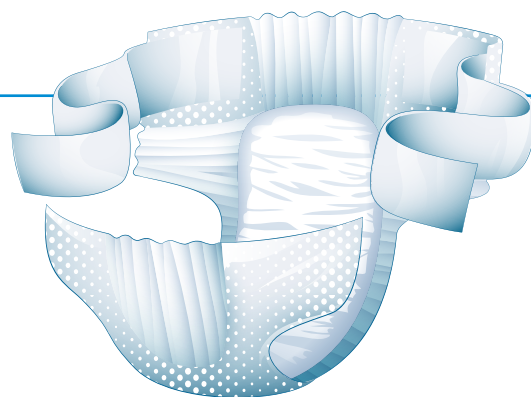
Moreover new products FARMEX AIR ensure superior comfort thanks to their softness and noiseless.



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)

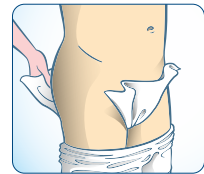


**NO ALCOHOL
HYPOALLERGENIC**

particularly
suitable for



Bedridden



Changing diapers

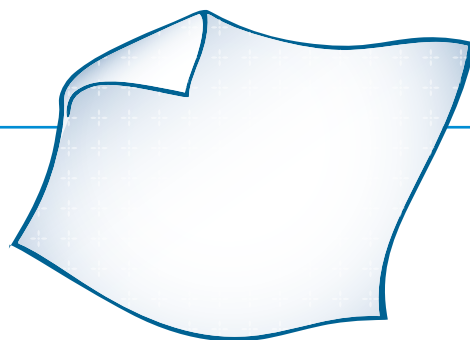
Ref	Ean	Size	Pcs/Pack	Pcs/Cart.
03JOL9100240	8004007910005	20 x 30	24	12 X 24



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.

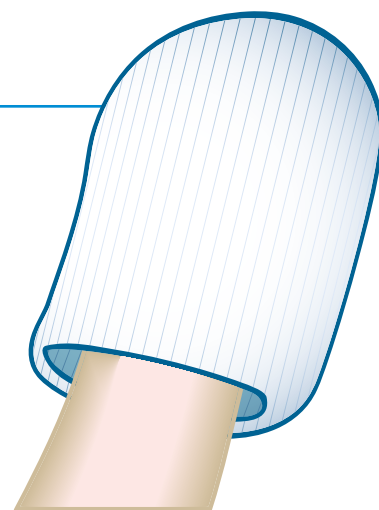


Ref	Ean	Size	Pcs/Pack	Pcs/Cart.
03JOL9121500	8004007912009	48 x 68 cm	150	6 X 150

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





SVAS BIOSANA S.p.A.

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FXS-021/2013-10/Rev.00



Ministero della Salute

DIREZIONE GENERALE DEI DISPOSITIVI MEDICI E DEL SERVIZIO
FARMACEUTICO
Uff. 3 - ex DGFDM

DGDMF/III/P/I.5.1.e.1/2016/16

VISTA la direttiva 93/42/CEE concernente i dispositivi medici;

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

VISTO il Decreto Legislativo n.46/97 e successive modifiche recante il recepimento della direttiva 93/42/CEE;

HAVING REGARD to the Legislative Decree n. 46/97 and its following amendments implementing Directive 93/42 EEC;

VISTA la richiesta con prot. 559- A- 08/01/2016 presentata dalla ditta **SVAS BIOSANA S.p.A.**, con sede in Via M. Perillo 34, 80047 San Giuseppe Vesuviano (NA), Italia, P. IVA IT04720630633;

HAVING REGARD to the request ref. 559-A-08/01/2016, submitted by the Company **SVAS BIOSANA S.p.A.**, located in Via M. Perillo 34, 80047 San Giuseppe Vesuviano (NA), Italy, VAT N° IT04720630633;

CONSIDERATO che la ditta ha effettuato i versamenti richiesti dal D.M. 07 Agosto 2012;

WHEREAS the Company paid the fees required by Ministerial Decree August 7th, 2012;

VISTI gli atti d'ufficio;

HAVING REGARD TO the official deeds;

**SI ATTESTA
IT IS ATTESTED**

che la Ditta **SVAS BIOSANA S.p.A.**, con sede in Via M. Perillo 34, 80047 San Giuseppe Vesuviano (NA), Italia, è il fabbricante e ha marcato CE come dispositivo medico, secondo le procedure previste dalla direttiva 93/42 CEE, il seguente prodotto:

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

PANNOLONE A MUTANDINA

Tale prodotto, in base all'art.4 della citata direttiva, è di libera circolazione e può essere immesso in commercio in Italia e in tutto il territorio dell'Unione Europea.

The above mentioned product, according to the art. 4 of the Directive 93/42/EEC, can freely circulate and can be placed on the market in Italy and all over the European Union.

Questo documento è rilasciato in unico originale a richiesta del fabbricante ai fini di esportazione di dispositivi medici **al di fuori della Unione Europea.**

*This document has been issued in a unique original version upon request of the manufacturer in order to export medical devices to **Countries outside European Union.***

Non è consentita la sua riproduzione o pubblicazione su carta, stampa, supporti elettronici o siti internet.

Ministero della Salute
DGDMF

0003401-P-25/01/2016
I.5.1.e.1/2016/16



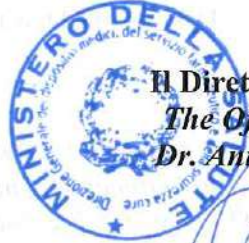
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Il Direttore dell'Ufficio
The Office Manager
Dr. Annamaria Donato

DP

Ministerul Sănătății

DIRECȚIA GENERALĂ PENTRU DISPOZITIVE MEDICALE ȘI SERVICII FARMACEUTICE

Art. 3 – DGDMSF

DGDMSF/III/P/I.5.1.e.1/2016/16

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. 559-A-08/01/2016 depusă de Societatea **SVAS BIOSANA S.p.A.**, cu sediul social înregistrat în Via M. Perillo 34, 80047 San Giuseppe Vesuviano (NA), Italia, TVA Nr. IT04720630633;

ÎNTRUCÂT Societatea a plătit toate taxele cerute prin Decretul Ministerial din 7 August, 2012;

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 San Giuseppe Vesuviano (NA), Italia, este producătorul următorului dispozitiv medical marcat CE:

PAMPERS

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 în versiune unică originală la cererea producătorului în scopul exportării dispozitivelor medicale și în **Țări care nu fac parte din Uniunea Europeană**.

Ministerul Sănătății
DGDMSF
0003401-P-25/01/2016
I.5.1.e. 1/2016/16
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Este permisă prezentarea sau trimiterea acestui document numai la solicitarea Autorităților Vamale sau din domeniul Sănătății din țara importatoare.

Șef Birou
Annamaria Donato

Ștampila și semnătura – indescifrabil

