

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

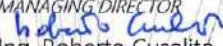
This Certificate should be made public only in integral form complete Annex 1

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

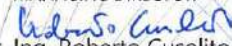
Divisione	Indirizzo Sede	Oggetto
DIVISIONE FARMEX	Via Colle, 104 – IT 80049 SOMMA VESUVIANA NA	Progettazione, produzione e distribuzione, anche a domicilio, di dispositivi medici: dispositivi di protezione e ausili per l'incontinenza, dispositivi per medicazioni generali e specialistiche. Progettazione 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


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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

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**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.

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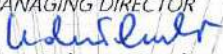
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L'AMMINISTRATORE DELEGATO

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
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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>
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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

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FARMEX



Adult incontinence devices



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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

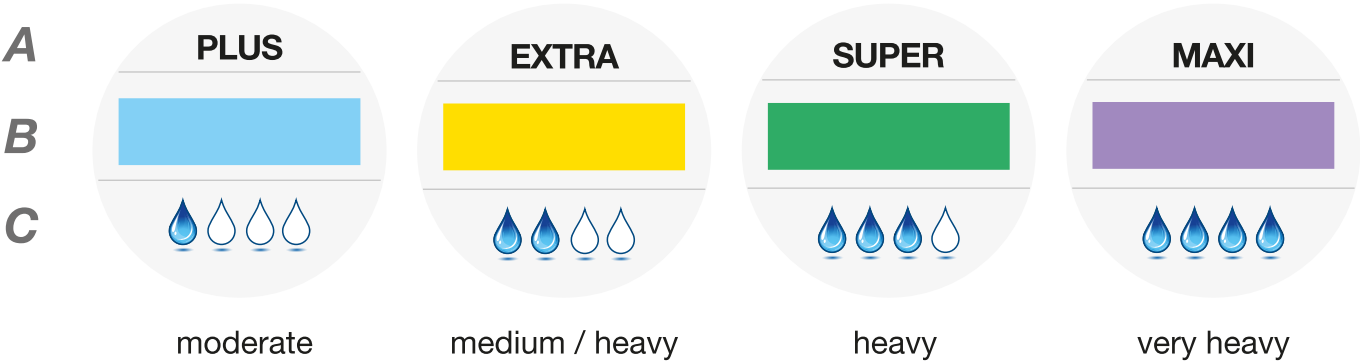
Farmex Incontinence Devices



(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.

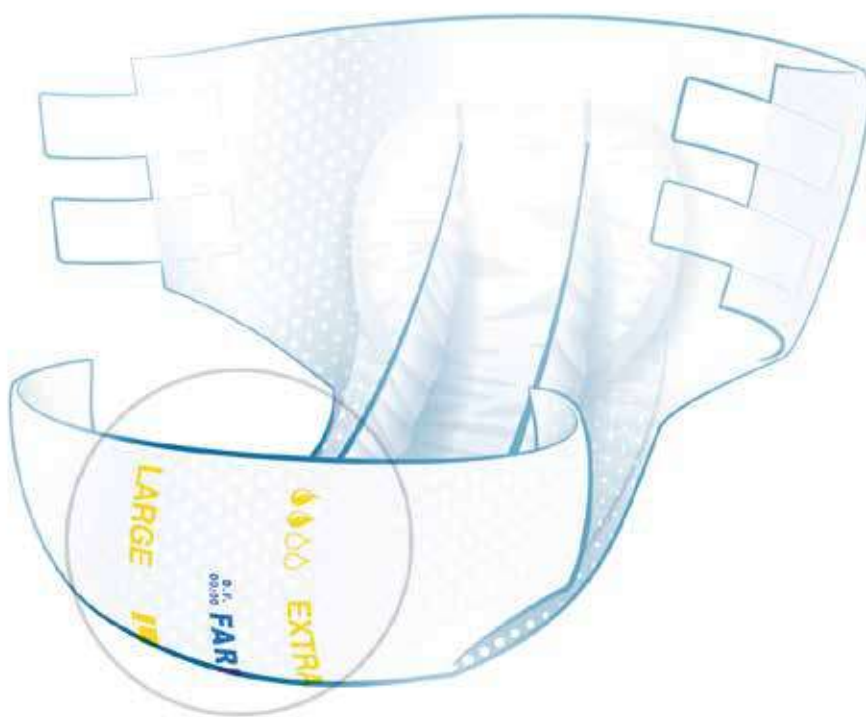
Our four different absorbency levels are identifiable by the color code and drops number printed.

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:

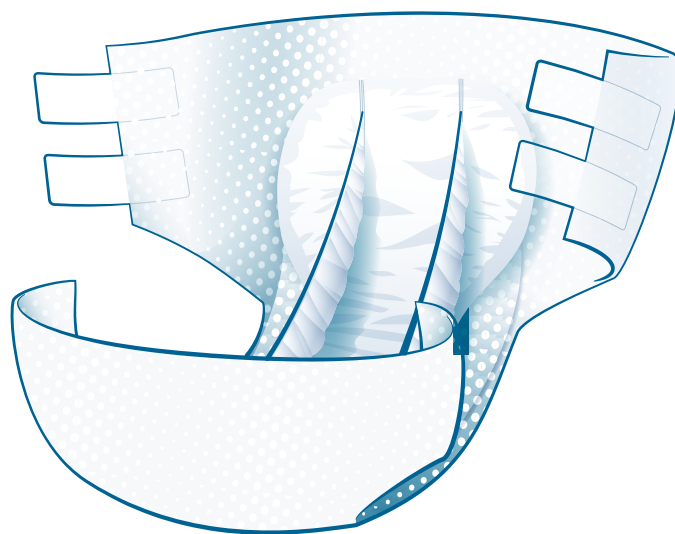
Reduces the risk of unpleasant odours.



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.)

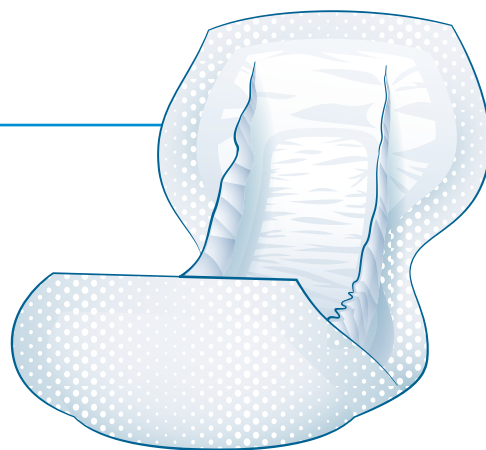


Ref	Ean	Paraph	N.T.N.	Size	Absorb.	Drops	Pcs/Pack	Pcs/Cart.
03JOL3103020	8004007310324	931436808	RIC. 09.30.04.006	M	PLUS		30	90
03JOL3103030	8004007310331	931436834	RIC. 09.30.04.003	L			30	90
03JOL3201510	8004007320019	931436846	09.30.04.009	S	EXTRA		15	90
03JOL3203020	8004007320323	931436911	09.30.04.006	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	4	20	80
03JOL2202000	8004007220203	931093470	09.30.04.015	EXTRA	4	20	80
03JOL2302000	8004007230202	931093482	09.30.04.012	SUPER	4	20	80
03JOL2402000	8004007240201	931093494	RIC. 09.30.04.012	MAXI	4	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

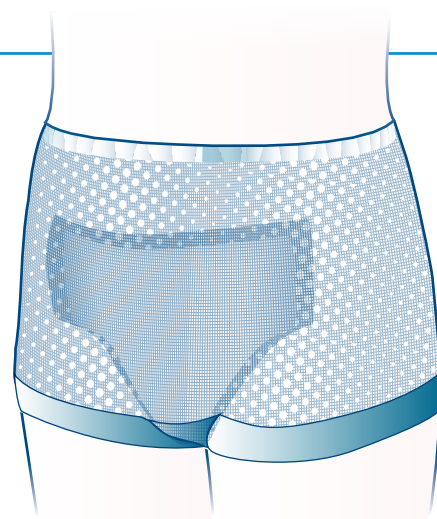
Ref	Ean	Paraph	N.T.N.	Size	Pcs/Pack	Pcs/Cart.
03JOL5001510	8004007500015	931437519	RIC. 18.12.15.006	40 X 60	15	90
03JOL5003020	8004007500329	931437533	RIC. 18.12.15.006	60 X 60	30	90
03JOL5003030	8004007500336	931437560	18.12.15.006	60 X 90	30	90
03JOL5003040	8004007500343	931437584	18.12.15.003	80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

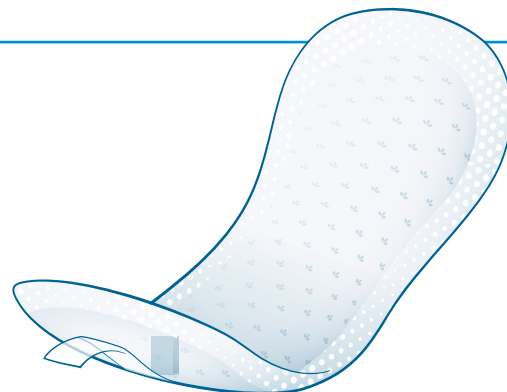


Ref	Ean	Paraph	N.T.N.	Size	Pcs/Pack	Pcs/Cart.
03JOL9600310	8004007960017	932230131	09.30.09.009	SMALL	30 x 3	90
03JOL9600320	8004007960024	932230143	09.30.09.006	MEDIUM	30 x 3	90
03JOL9600330	8004007960031	932230156	09.30.09.003	LARGE	30 x 3	90
03JOL9600340	8004007960048	932230168	RIC. 09.30.09.003	EXTRALARGE	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	4	12	144
03JOL2001020	8004007200113	932229851	RIC. 09.30.04.018	EXTRA	3	10	100
03JOL2003020	8004007200311	932229863	RIC. 09.30.04.018	EXTRA	3	30	360
03JOL2001030	8004007200120	932229875	RIC. 09.30.04.018	SUPER	3	10	120
03JOL2003030	8004007200328	932229887	RIC. 09.30.04.018	SUPER	3	30	180
03JOL2001440	8004007200830	932229899	RIC. 09.30.04.018	SUPER PLUS	3	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	3	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.

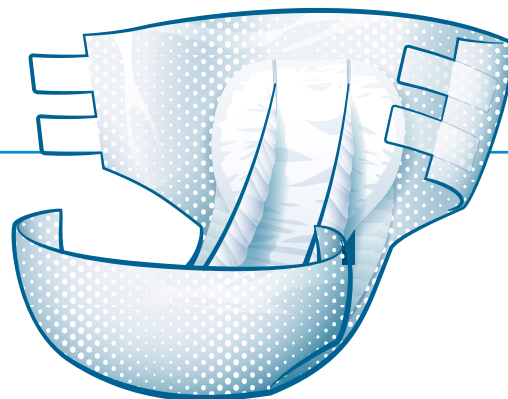
Combination between breathable backsheet and the emollient lotion guarantees to AIR DERMO products an efficient derma-protection system to avoid skin irritation.



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.)



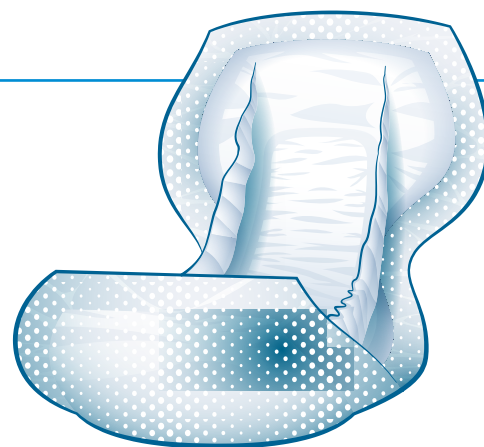
Ref	Ean	Paraph	N.T.N.	Size	Absorb.	Drops	Pcs/Pack	Pcs/Cart.
03JOL3211510	8004007321016	932229901	09.30.04.009	S	EXTRA		15	90
03JOL3213020	8004007321320	932229913	09.30.04.006	M			30	90
03JOL3213030	8004007321337	932229925	09.30.04.003	L			30	90
03JOL3213040	8004007321344	932229937	RIC. 09.30.04.003	XL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

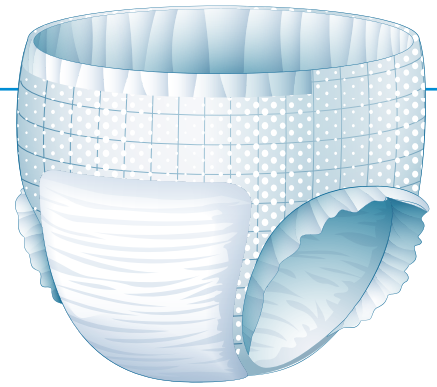


Ref	Ean	Paraph	N.T.N.	Absorb.	Drops	Pcs/Pack	Pcs/Cart.
03JOL2112000	8004007211201	932230004	09.30.04.018	PLUS		20	80
03JOL2212000	8004007221200	932230016	09.30.04.015	EXTRA		20	80
03JOL2312000	8004007231209	932230030	09.30.04.012	SUPER		20	80
03JOL2412000	8004007241208	932230042	RIC. 09.30.04.012	MAXI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

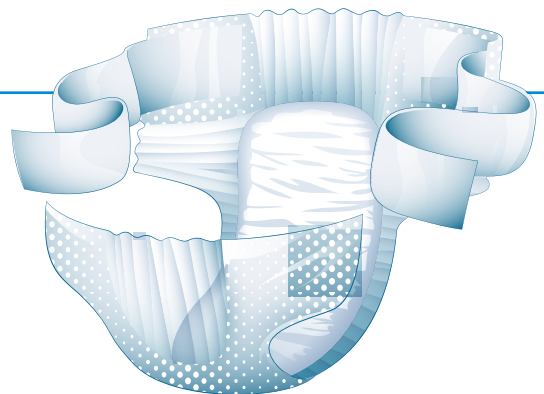
Moreover new products FARMEX AIR ensure superior comfort thanks to their softness and noiseless.



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)

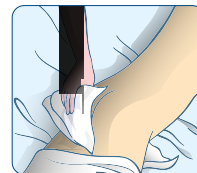
Chamomile and Cornflower Extract (Rejuvenating, soothing and protecting effect)

Natural Bisabolol added (Refreshing and moisturizing)

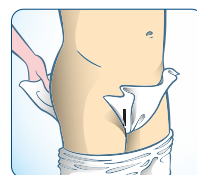


**NO ALCOHOL
HYPOALLERGENIC**

particularly
suitable for



Bedridden



Changing diapers

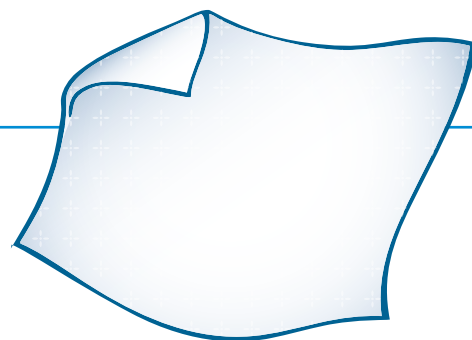
Ref	Ean	Size	Pcs/Pack	Pcs/Cart.
03JOL9100240	8004007910005	20 x 30	24	12 X 24



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.

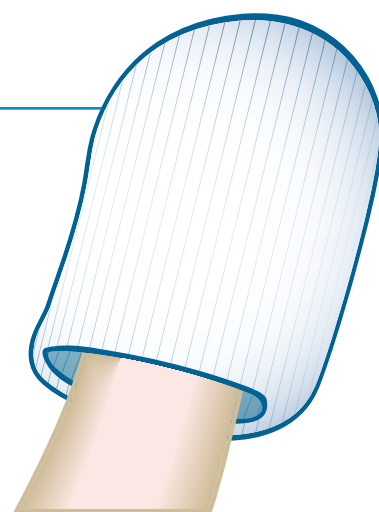


Ref	Ean	Size	Pcs/Pack	Pcs/Cart.
03JOL9121500	8004007912009	48 x 68 cm	150	6 X 150

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





SVAS BIOSANA S.p.A.

Via Colle, 104 - 80049 Somma Vesuviana
Napoli - Italy
Tel. +39 081 8931992 - Fax +39 081 8931807
www.svas.it - svas.biosana@svas.it

FXS-021/2013-10/Rev.00



Ministero della Salute

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

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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Ne è consentita la sola esibizione o consegna alle autorità doganali o sanitarie del paese di importazione.

It is only allowed to show or to delivery it, upon request of the Customs or Health Competent Authorities of the importing country.



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/PII.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.I.e. 1/2016/16

173766550

Nu este permisă reproducerea sau publicarea prezentului document pe suport de hârtie, în presă, pe suport electronic sau site-uri web.

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



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

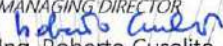
This Certificate should be made public only in integral form complete Annex 1

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.

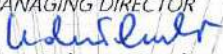
Il presente Certificato deve essere reso pubblico solo in forma integrale completo dell'Allegato 1

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° 122B
SGA N° 020D ISP N° 075E
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FARMEX



Adult incontinence devices



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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.



Product Identification Guide

Farmex Incontinence Devices

FARMEX
Standard products

FARMEX AIR DERMO
Breathable with
Derma-protection products

FARMEX AIR
Breathable products

(Degrees of incontinence)

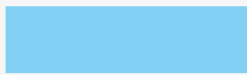
Absorbency level

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

A

PLUS

B



C



moderate

EXTRA



medium / heavy

SUPER



heavy

MAXI



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.

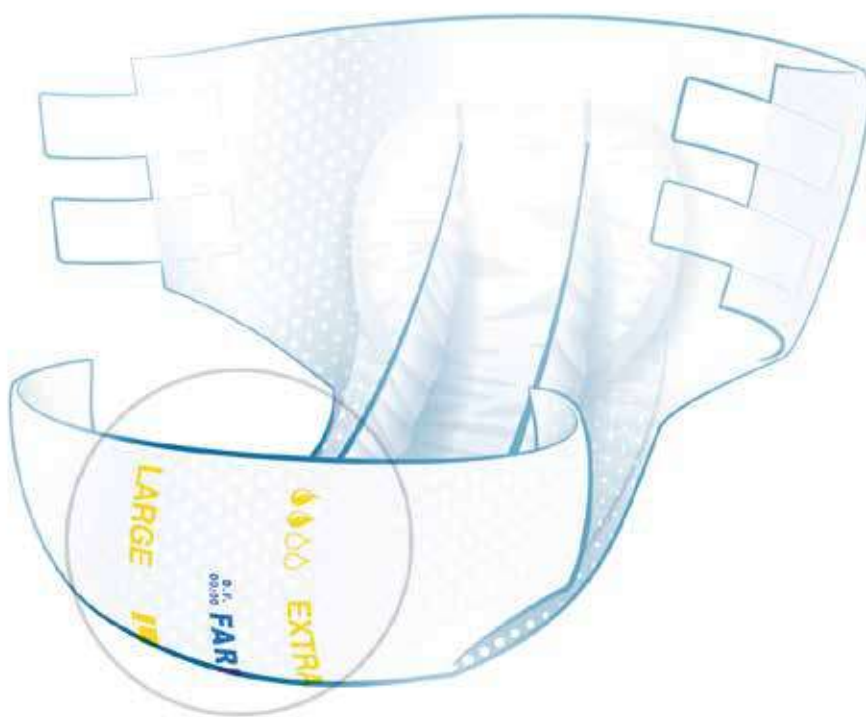
Our four different absorbency levels are identifiable by the color code and drops number printed.

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:

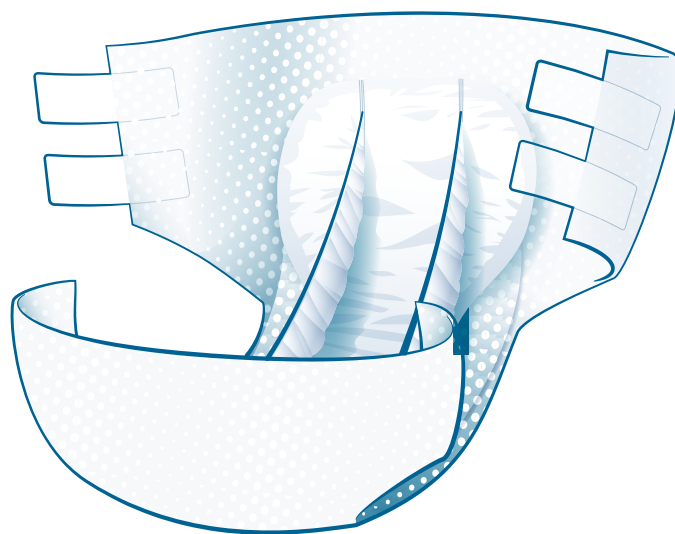
Reduces the risk of unpleasant odours.



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.)

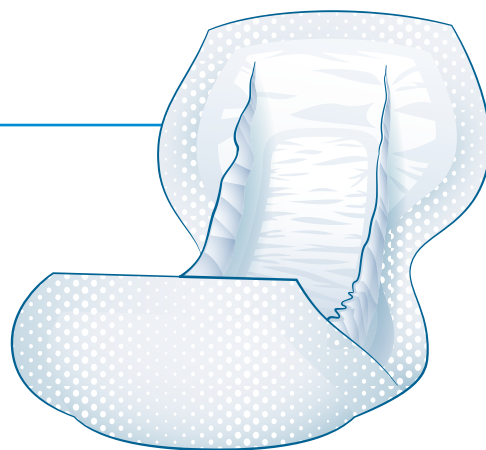


Ref	Ean	Paraph	N.T.N.	Size	Absorb.	Drops	Pcs/Pack	Pcs/Cart.
03JOL3103020	8004007310324	931436808	RIC. 09.30.04.006	M	PLUS		30	90
03JOL3103030	8004007310331	931436834	RIC. 09.30.04.003	L			30	90
03JOL3201510	8004007320019	931436846	09.30.04.009	S	EXTRA		15	90
03JOL3203020	8004007320323	931436911	09.30.04.006	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	💧💧💧	20	80
03JOL2202000	8004007220203	931093470	09.30.04.015	EXTRA	💧💧💧	20	80
03JOL2302000	8004007230202	931093482	09.30.04.012	SUPER	💧💧💧	20	80
03JOL2402000	8004007240201	931093494	RIC. 09.30.04.012	MAXI	💧💧💧	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

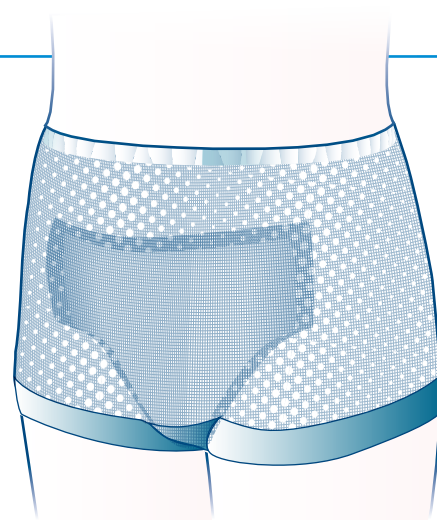
Ref	Ean	Paraph	N.T.N.	Size	Pcs/Pack	Pcs/Cart.
03JOL5001510	8004007500015	931437519	RIC. 18.12.15.006	40 X 60	15	90
03JOL5003020	8004007500329	931437533	RIC. 18.12.15.006	60 X 60	30	90
03JOL5003030	8004007500336	931437560	18.12.15.006	60 X 90	30	90
03JOL5003040	8004007500343	931437584	18.12.15.003	80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

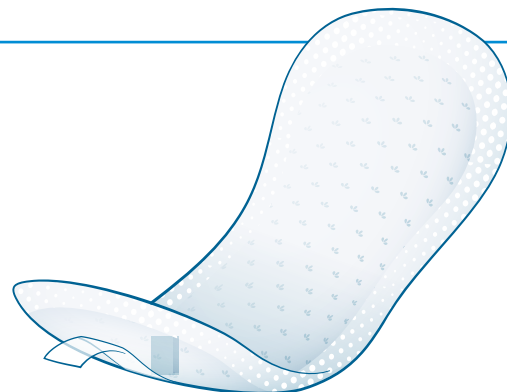


Ref	Ean	Paraph	N.T.N.	Size	Pcs/Pack	Pcs/Cart.
03JOL9600310	8004007960017	932230131	09.30.09.009	SMALL	30 x 3	90
03JOL9600320	8004007960024	932230143	09.30.09.006	MEDIUM	30 x 3	90
03JOL9600330	8004007960031	932230156	09.30.09.003	LARGE	30 x 3	90
03JOL9600340	8004007960048	932230168	RIC. 09.30.09.003	EXTRALARGE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

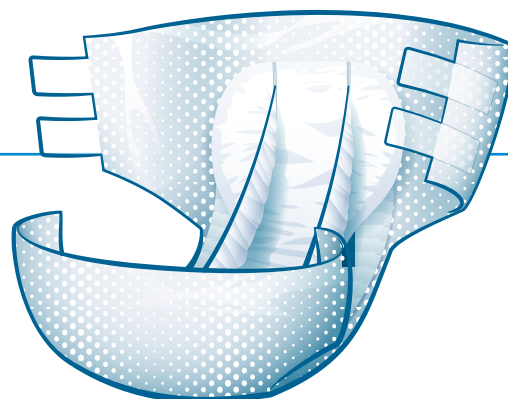
Combination between breathable backsheet and the emollient lotion guarantees to AIR DERMO products an efficient derma-protection system to avoid skin irritation.



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.)



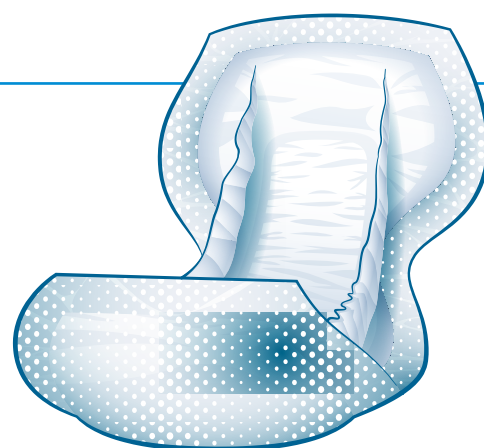
Ref	Ean	Paraph	N.T.N.	Size	Absorb.	Drops	Pcs/Pack	Pcs/Cart.
03JOL3211510	8004007321016	932229901	09.30.04.009	S	EXTRA		15	90
03JOL3213020	8004007321320	932229913	09.30.04.006	M			30	90
03JOL3213030	8004007321337	932229925	09.30.04.003	L			30	90
03JOL3213040	8004007321344	932229937	RIC. 09.30.04.003	XL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

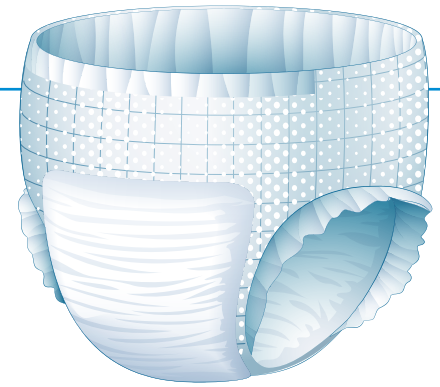


Ref	Ean	Paraph	N.T.N.	Absorb.	Drops	Pcs/Pack	Pcs/Cart.
03JOL2112000	8004007211201	932230004	09.30.04.018	PLUS		20	80
03JOL2212000	8004007221200	932230016	09.30.04.015	EXTRA		20	80
03JOL2312000	8004007231209	932230030	09.30.04.012	SUPER		20	80
03JOL2412000	8004007241208	932230042	RIC. 09.30.04.012	MAXI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

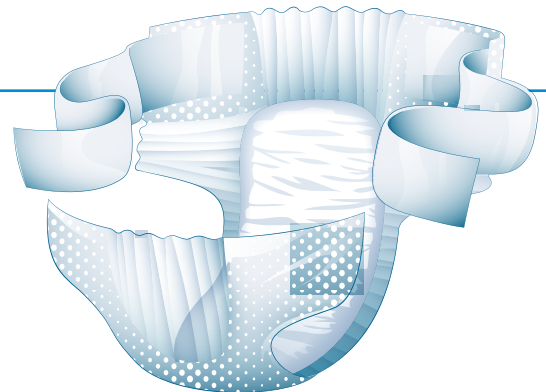
Moreover new products FARMEX AIR ensure superior comfort thanks to their softness and noiseless.



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)

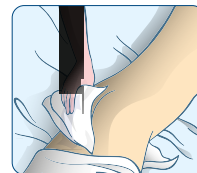
Chamomile and Cornflower Extract (Rejuvenating, soothing and protecting effect)

Natural Bisabolol added (Refreshing and moisturizing)

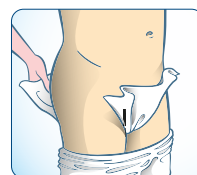


**NO ALCOHOL
HYPOALLERGENIC**

particularly
suitable for



Bedridden



Changing diapers

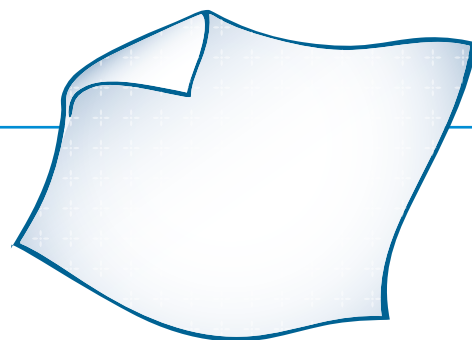
Ref	Ean	Size	Pcs/Pack	Pcs/Cart.
03JOL9100240	8004007910005	20 x 30	24	12 X 24



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.

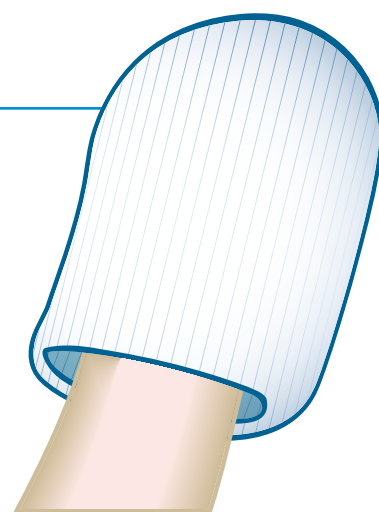


Ref	Ean	Size	Pcs/Pack	Pcs/Cart.
03JOL9121500	8004007912009	48 x 68 cm	150	6 X 150

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





SVAS BIOSANA S.p.A.

Via Colle, 104 - 80049 Somma Vesuviana
Napoli - Italy
Tel. +39 081 8931992 - Fax +39 081 8931807
www.svas.it - svas.biosana@svas.it

FXS-021/2013-10/Rev.00



Ministero della Salute

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

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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It is not allowed any reproduction or publication of this document by paper, press, electronic base or websites.

Ne è consentita la sola esibizione o consegna alle autorità doganali o sanitarie del paese di importazione.

It is only allowed to show or to delivery it, upon request of the Customs or Health Competent Authorities of the importing country.



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/PII.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.I.e. 1/2016/16

173766550

Nu este permisă reproducerea sau publicarea prezentului document pe suport de hârtie, în presă, pe suport electronic sau site-uri web.

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



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

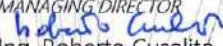
This Certificate should be made public only in integral form complete Annex 1

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.

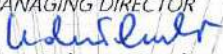
Il presente Certificato deve essere reso pubblico solo in forma integrale completo dell'Allegato 1

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° 122B
SGA N° 020D ISP N° 075E
PRS N° 097C

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
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FARMEX



Adult incontinence devices



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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.



Product Identification Guide

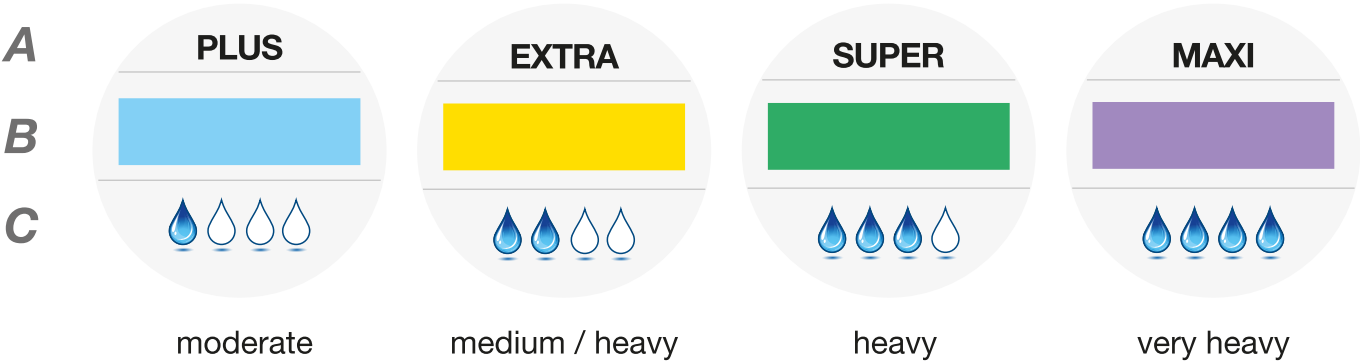
Farmex Incontinence Devices



(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.

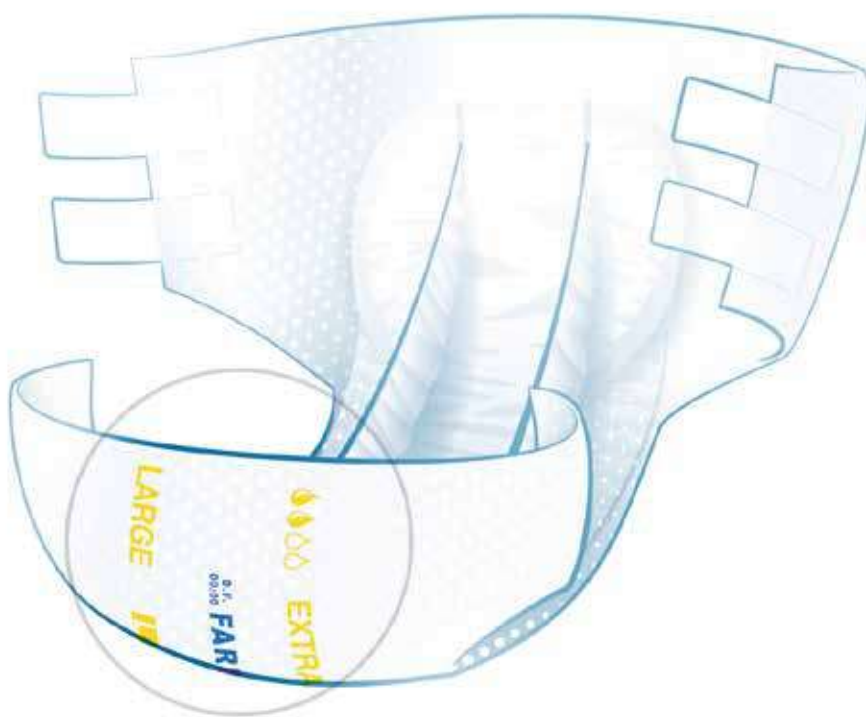
Our four different absorbency levels are identifiable by the color code and drops number printed.

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:

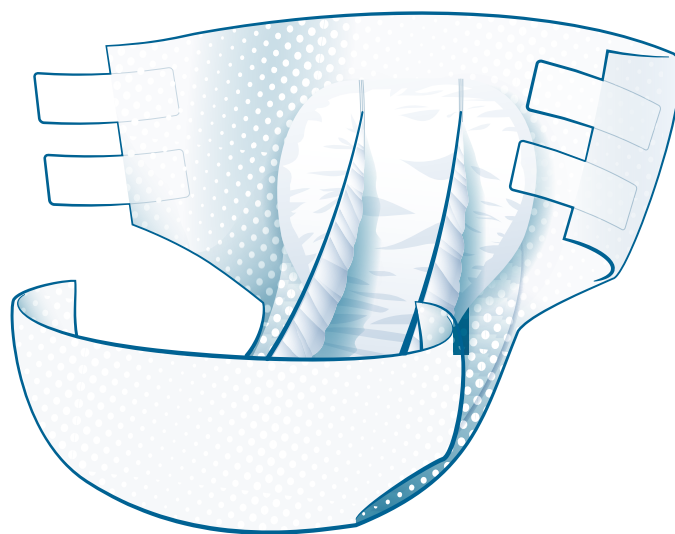
Reduces the risk of unpleasant odours.



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.)

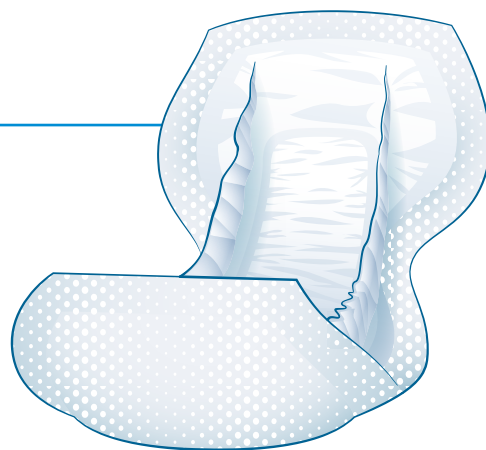


Ref	Ean	Paraph	N.T.N.	Size	Absorb.	Drops	Pcs/Pack	Pcs/Cart.
03JOL3103020	8004007310324	931436808	RIC. 09.30.04.006	M	PLUS		30	90
03JOL3103030	8004007310331	931436834	RIC. 09.30.04.003	L			30	90
03JOL3201510	8004007320019	931436846	09.30.04.009	S	EXTRA		15	90
03JOL3203020	8004007320323	931436911	09.30.04.006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

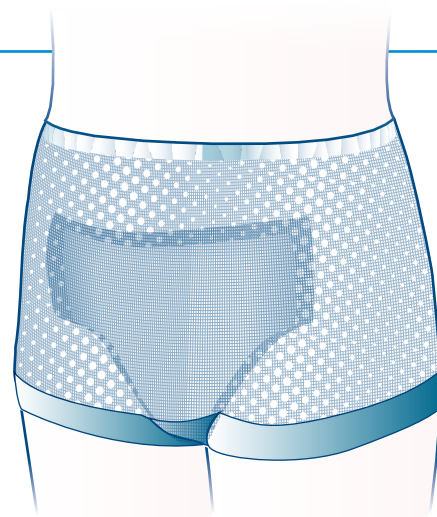
Ref	Ean	Paraph	N.T.N.	Size	Pcs/Pack	Pcs/Cart.
03JOL5001510	8004007500015	931437519	RIC. 18.12.15.006	40 X 60	15	90
03JOL5003020	8004007500329	931437533	RIC. 18.12.15.006	60 X 60	30	90
03JOL5003030	8004007500336	931437560	18.12.15.006	60 X 90	30	90
03JOL5003040	8004007500343	931437584	18.12.15.003	80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

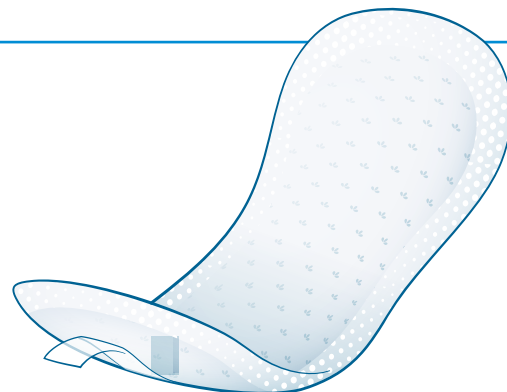


Ref	Ean	Paraph	N.T.N.	Size	Pcs/Pack	Pcs/Cart.
03JOL9600310	8004007960017	932230131	09.30.09.009	SMALL	30 x 3	90
03JOL9600320	8004007960024	932230143	09.30.09.006	MEDIUM	30 x 3	90
03JOL9600330	8004007960031	932230156	09.30.09.003	LARGE	30 x 3	90
03JOL9600340	8004007960048	932230168	RIC. 09.30.09.003	EXTRALARGE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

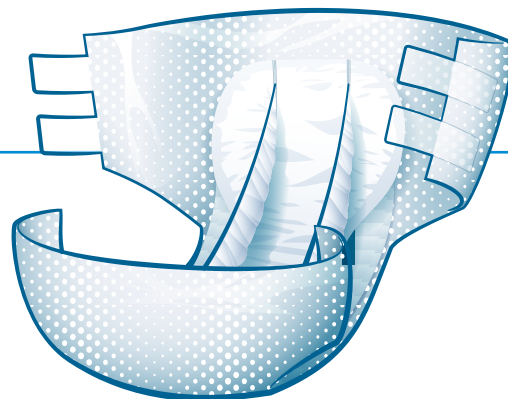
Combination between breathable backsheet and the emollient lotion guarantees to AIR DERMO products an efficient derma-protection system to avoid skin irritation.



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.)



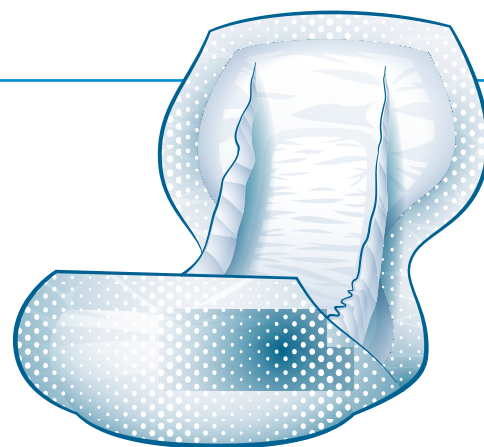
Ref	Ean	Paraph	N.T.N.	Size	Absorb.	Drops	Pcs/Pack	Pcs/Cart.
03JOL3211510	8004007321016	932229901	09.30.04.009	S	EXTRA		15	90
03JOL3213020	8004007321320	932229913	09.30.04.006	M			30	90
03JOL3213030	8004007321337	932229925	09.30.04.003	L			30	90
03JOL3213040	8004007321344	932229937	RIC. 09.30.04.003	XL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

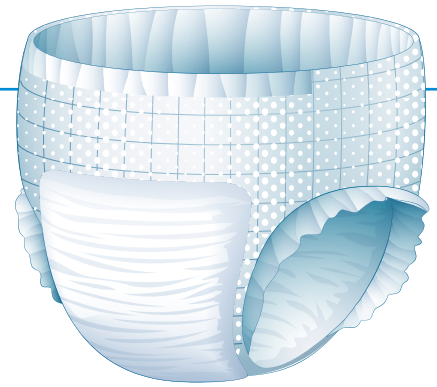


Ref	Ean	Paraph	N.T.N.	Absorb.	Drops	Pcs/Pack	Pcs/Cart.
03JOL2112000	8004007211201	932230004	09.30.04.018	PLUS		20	80
03JOL2212000	8004007221200	932230016	09.30.04.015	EXTRA		20	80
03JOL2312000	8004007231209	932230030	09.30.04.012	SUPER		20	80
03JOL2412000	8004007241208	932230042	RIC. 09.30.04.012	MAXI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

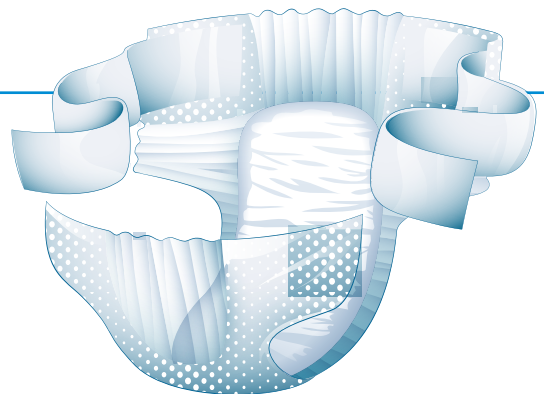
Moreover new products FARMEX AIR ensure superior comfort thanks to their softness and noiseless.



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)

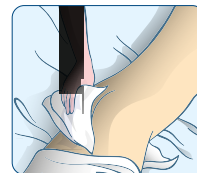
Chamomile and Cornflower Extract (Rejuvenating, soothing and protecting effect)

Natural Bisabolol added (Refreshing and moisturizing)

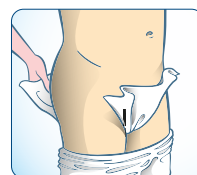


**NO ALCOHOL
HYPOALLERGENIC**

particularly
suitable for



Bedridden



Changing diapers

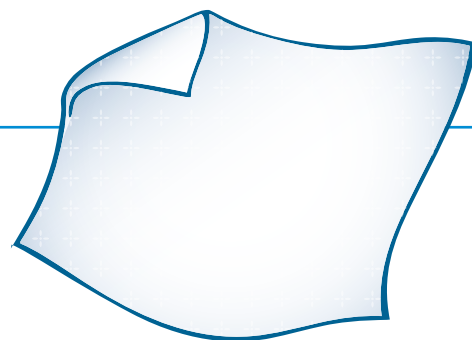
Ref	Ean	Size	Pcs/Pack	Pcs/Cart.
03JOL9100240	8004007910005	20 x 30	24	12 X 24



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.

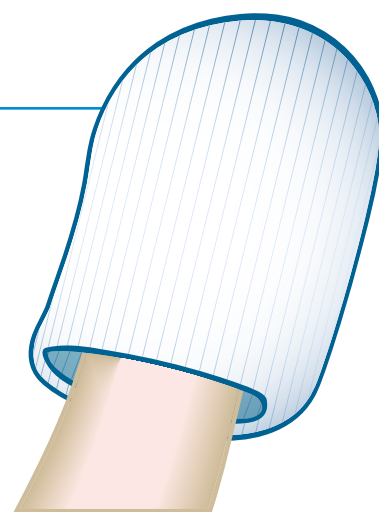


Ref	Ean	Size	Pcs/Pack	Pcs/Cart.
03JOL9121500	8004007912009	48 x 68 cm	150	6 X 150

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





SVAS BIOSANA S.p.A.

Via Colle, 104 - 80049 Somma Vesuviana
Napoli - Italy
Tel. +39 081 8931992 - Fax +39 081 8931807
www.svas.it - svas.biosana@svas.it

FXS-021/2013-10/Rev.00



Ministero della Salute

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

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



173766550

It is not allowed any reproduction or publication of this document by paper, press, electronic base or websites.

Ne è consentita la sola esibizione o consegna alle autorità doganali o sanitarie del paese di importazione.

It is only allowed to show or to delivery it, upon request of the Customs or Health Competent Authorities of the importing country.



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/PII.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.I.e. 1/2016/16

173766550

Nu este permisă reproducerea sau publicarea prezentului document pe suport de hârtie, în presă, pe suport electronic sau site-uri web.

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



EC Certification



EC DESIGN EXAMINATION CERTIFICATE Directive 93/42/EEC for Medical Devices, Annex II (4)

We hereby declare that a design examination has been carried out on the device(s) listed hereafter following the requirements of the UK national legislation to which the undersigned is subjected, transposing Annex II Section 4 of the Directive 93/42/EEC on medical devices. We certify that the design of the device(s) listed hereafter conforms with the relevant provisions of Annex II Section 4 of the aforementioned legislation, and the result entitles the organization to use the CE 0473 marking on those products*.

SMITHS MEDICAL ASD INC.

1265 Grey Fox Road, St Paul, MN 55112, USA

1. PORT-A-CATH® Peritoneal Implantable Access System
2. PORT-A-CATH® II Fluoro-Free® Implantable Venous Access
3. PORT-A-CATH® & PORT-A-CATH® II Epidural or Intraspinal Implantable Access System
4. P.A.S. PORT® Systems Fluoro-Free® Implantable Venous Access Systems
5. PORT-A-CATH® / PORT-A-CATH® II Vascular Access Systems
6. P.A.S. PORT® Systems Implantable Venous Access Systems
7. ProPort® Implantable Venous Access Systems
8. PORT-A-CATH®, PORT-A-CATH® II, and P.A.S. PORT® T2 POWER P.A.C.™ Implantable Venous Access Systems with Power Injection Capability
9. PORT-A-CATH® II and P.A.S. PORT® T2 POWER P.A.C.™ Fluoro-Free® Implantable Venous Access Systems with Power Injection Capability

*For CE marking the class III devices covered by this certificate, an EC certificate according to Annex II (3) is also required.

Certificate Number: 058.1-03 DE
Initial Certification Date: 09 August 1995
Certificate Effective Date: 13 May 2016
Certificate Expiry Date: 08 August 2020

Barry A. Fitch

Head of Notified Body

AMTAC Certification Services Limited, Milton Keynes, UK
This certificate is the property of AMTAC Certification Services Ltd



In the issuance of this certificate, Intertek assumes no liability to any party other than to the Client, and then only in accordance with the agreed upon Certification Agreement. This certificate's validity is subject to the organization maintaining their system in accordance with Intertek's requirements for systems certification. Validity may be confirmed via email at certificate.validation@intertek.com or by scanning the code to the right with a smartphone.

This Certificate is for the exclusive use of AMTAC's client and is provided pursuant to the agreement between AMTAC and its Client. AMTAC's responsibility and liability are limited to the terms and conditions of the agreement. AMTAC assumes no liability to any party, other than to the Client in accordance with the agreement, for any loss, expense or damage occasioned by the use of this Certificate. Only the Client is authorized to permit copying or distribution of this Certificate. Any use of the AMTAC name or one of its marks for the sale or advertisement of the tested material, product or service must first be approved in writing by AMTAC.

The certificate remains the property of Intertek, to whom it must be returned upon request.

The certification is subject to the organization maintaining their system in compliance with the regulations stated in this certificate, allowing regular assessments and following the contracted requirements of the Notified Body.

AMTAC Certification Services Limited is a Notified Body according to Directive 93/42/EEC for medical devices, with identification number 0473.

Certificat CE

CERTIFICAT DE EXAMINARE CE DE TIP Directiva 93/42/CEE pentru Dispozitive Medicale, Anexa II (4)

Declarăm prin prezenta că a fost efectuată o examinare a tipului dispozitivului(elor) specificate în continuare în prezenta, conform cerințelor legislației naționale britanice la care este supusă subsemnata, cu transpunerea Anexei II Secțiunea 4 la Directiva 93/42/CEE privind dispozitivele medicale. Certificăm că tipul dispozitivului(elor) menționate în continuare în prezenta este în conformitate cu prevederile relevante ale Anexei II Secțiunea 4 din legislația menționată mai sus și, prin urmare, organizația are dreptul de a utiliza marcajul CE 0473 pe produsele specificate mai jos *.

SMITHS MEDICAL ASD INC.

1265 Grey Fox Road, St Paul, MN 55112, SUA

1. Sistem implantabil de acces peritoneal PORT-A-CATH®
2. Acces implantabil venos PORT-A-CATH® II Fluoro-Free®
3. Sistem implantabil de acces epidural sau intraspinal PORT-A-CATH® & PORT-A-CATH® II
4. Sisteme implantabile de acces venos P.A.S. PORT® Systems Fluoro-Free®
5. Sisteme de acces vascular PORT-A-CATH® / PORT-A-CATH® II
6. Sisteme implantabile de acces venos P.A.S. PORT®
7. Sisteme implantabile de acces venos ProPort®
8. Sisteme implantabile de acces venos cu capacitate de injectare PORT-A-CATH®, PORT-A-CATH® II, și P.A.S. PORT® T2 POWER P.A.C.™
9. Sisteme implantabile de acces venos cu capacitate de injectare PORT-A-CATH® II and P.A.S. PORT® T2 POWER P.A.C.™ Fluoro-Free®

*Pentru a primi marcajul CE, dispozitivele din clasa III acoperite de acest certificat necesită și un certificat CE conform Anexei II (3).

Număr Certificat: Inițial 058.1-03 DE
Data Certificării: 09 August 1995
Data efectivă a certificării: 13 Mai 2016
Data expirării certificării: 08 August 2020

Semnătură indescifrabilă

Barry A. Fitch
Directorul Organismului Notificat
AMTAC Certification Services Limited, Milton Keynes, UK
Acest certificat este proprietatea AMTAC Certification Services Ltd



La eliberarea acestui certificat, Intertek nu își asumă responsabilitatea față de oricare parte alta decât Clientul, și atunci doar în conformitate cu Acordul de Certificare acordat. Valabilitatea acestui certificat este supusă menținerii, de către organizație, a sistemului în conformitate cu cerințele Intertek pentru certificarea sistemelor. Valabilitatea acestuia poate fi confirmată la certificate.validation@intertek.com sau prin scanarea codului din dreapta cu un smartphone.

Acest Certificat este pentru uzul exclusiv al clientului AMTAC și este eliberat în urma acordului dintre AMTAC și Clientul acesteia. Responsabilitatea și obligația AMTAC sunt limitate la termenii și condițiile acordului. AMTAC nu își asumă responsabilitatea față de oricare parte alta decât Clientul în conformitate cu acordul, pentru nicio pierdere, cheltuielă sau daună ocazionate prin utilizarea acestui Certificat. Clientul este singurul autorizat pentru a permite reproducerea sau distribuirea acestui Certificat. Orice utilizare a numelui AMTAC sau a uneia dintre mărcile sale pentru vânzare sau promovare a materialului testat, produs sau servicii, va fi aprobat în prealabil în scris de către AMTAC.

Acest certificat rămâne proprietatea Intertek, căreia îi va fi returnat la cerere.

Certificarea este supusă menținerii, de către organizație, a sistemului acesteia în conformitate cu regulamentele specificate în acest certificat și permite evaluări regulate și în urma cerințelor contractate ale Organismului Notificat.
AMTAC Certification Services Limited este Organism Notificat conform Directivei 93/42/CEE pentru dispozitivele medicale, cu număr de identificare 0473.



EC Certification

Intertek

FULL QUALITY ASSURANCE SYSTEM
Directive 93/42/EEC for Medical Devices, Annex II excluding (4)

We hereby declare that an examination of the under mentioned full quality assurance system has been carried out following the requirements of the UK national legislation to which the undersigned is subjected, transposing Annex II (with the exemption of section 4) of the Directive 93/42/EEC on medical devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive, and the result entitles the organization to use the CE 0473 marking on those products listed below.

SMITHS MEDICAL, ASD, INC

160 Weymouth Street, Rockland, MA 02370, USA

Warming Units, Blankets and Accessories
Infusion Sets

Aesophageal Stethoscopes; 9 to 24 Fr

Aerosol cloud enhancer

Bypass valve for HME/HCH

Low-flow breathing exerciser

Incentive spirometers

Positive airway pressure therapy system

Vibratory positive expiratory pressure therapy systems with or without small volume nebulizer

Positive expiratory pressure therapy system

As per the attached schedule

Certificate Number: 171 CE
Initial Certification Date: 24 July 1998
Certificate Effective Date: 24 July 2013
Certificate Expiry Date: 23 July 2018

Brian Johnson ~ Authorised Signatory

AMTAC Certification Services Limited, Milton Keynes, UK

This certificate is the property of AMTAC Certification Services Ltd a wholly owned subsidiary of Intertek Holdings Ltd

In the issuance of this certificate, Intertek assumes no liability to any party other than to the Client, and then only in accordance with the agreed upon Certification Agreement. This certificate's validity is subject to the organization maintaining their system in accordance with Intertek's requirements for systems certification. Validity may be confirmed via email at certificate.validation@intertek.com or by scanning the code to the right with a smartphone.

This Certificate is for the exclusive use of AMTAC's client and is provided pursuant to the agreement between AMTAC and its Client. AMTAC's responsibility and liability are limited to the terms and conditions of the agreement. AMTAC assumes no liability to any party, other than to the Client in accordance with the agreement, for any loss, expense or damage occasioned by the use of this Certificate. Only the Client is authorized to permit copying or distribution of this Certificate. Any use of the AMTAC name or one of its marks for the sale or advertisement of the tested material, product or service must first be approved in writing by AMTAC.

The certificate remains the property of Intertek, to whom it must be returned upon request.

The certification is subject to the organization maintaining their system in compliance with the regulations stated in this certificate, allowing regular assessments and following the contracted requirements of the Notified Body.

AMTAC Certification Services Limited is a Notified Body according to Directive 93/42/EEC for medical devices, with identification number 0473.



PRODUCT SCHEDULE FOR CERTIFICATE 171 CE
SMITHS MEDICAL ASD, INC

Intertek

Slow Flow Fluid Warming Unit
Slow Flow I.V. Infusion Sets
Slow Flow Fluid Warming Unit Accessories
Fluid Warming Units, Fast Flow
Fast Flow Accessory Equipment
Fast Flow I.V. Infusion Sets, Sterile fluid path
Fast Flow I.V. Infusion Sets, Accessory
Irrigating Sets, disposable
Slow Flow Fluid Warming units with PEMS (Programmable Medical Systems)
Slow Flow I.V. Infusion Sets for PEMS units
Convective Warming units
Convective Warming Blankets Sterile
Convective Warming Blankets Non-Sterile
Convective Warming Accessories
General Purpose Temperature Probes, Esophageal/Rectal 9 to 12 French
Myocardial Temperature Probes, Foley Catheter 3 to 30 mm
Temperature Probes, Foley Catheter 8 to 18 French
Temperature Probes, Skin, adult to neonate
Temperature Probes, Tympanic; adult and paediatric
Aesophageal Stethoscopes; 8 to 24 Fr
Aerosol cloud enhancer
Bypass valve for HME/HCH
Low-flow breathing exerciser
Incentive spirometers
Positive airway pressure therapy system
Vibratory positive expiratory pressure therapy systems with or without small volume nebulizer
Positive expiratory pressure therapy system

Initial Certification Date: 24 July 1998
Certificate Effective Date: 24 July 2013

 Brian Johnson ~ Authorized Signatory

Page 1 of 1



Certificare CE

Intertek

SISTEM COMPLET DE ASIGURARE A CALITĂȚII

Directiva 93/42/CEE privind dispozitivele medicale, Anexa II excluzând (4)

Declarăm prin prezenta că o examinare a sistemului complet de asigurare a calității menționat mai jos a fost efectuată conform cerințelor legislației naționale din UK care ne guvernează, transpunând Anexa II (cu excepția secțiunii 4) a Directivei 93/42/CEE privind dispozitivele medicale. Certificăm că sistemul complet de asigurare a calității este în conformitate cu prevederile relevante ale directivei menționate mai sus, iar rezultatul îi dă dreptul organizației să folosească marcajul CE 0473 pe produsele enumerate mai jos.

SMITHS MEDICAL, ASD, INC

160 Weymouth Street Rockland, MA 02370 SUA

Unități de încălzire, pături și accesorii

Perfuzoare

Stetoscoape esofagiene, 9-24 Fr

Amplificator nor aerosoli

Valvă bypass pentru HME/HCH

Aparat pentru exerciții respiratorii cu flux redus

Spirometre de stimulare

Sistem de terapie cu presiune pozitivă a căilor respiratorii

Sisteme de terapie cu presiune expiratorie pozitivă vibratoare cu sau fără nebulizator de volum mic

Sistem de terapie cu presiune expiratorie pozitivă

Conform listei atașate

Număr Certificat:	171 CE
Data inițială a certificării:	24 Iulie 1998
Data intrării în vigoare a certificatului:	24 Iulie 2013
Data expirării certificatului:	24 Iulie 2018

Brian Johnson - Semnatar autorizat – Semnătură indescifrabilă

AMTAC Certification Services Limited, Milton Keynes, UK

Prezentul Certificat este proprietatea AMTAC Certification Services Ltd o filială deținută integral de Intertek Holdings Ltd

În emiterea prezentului certificat, AMTAC nu își asumă nicio răspundere către nicio parte, alta decât Clientul și atunci numai în conformitate cu Acordul de Certificare convenit. Valabilitatea prezentului certificat este condiționată de menținerea sistemului în conformitate cu cerințele Intertek pentru certificarea sistemelor. Valabilitatea poate fi confirmată prin email la certificate.validation@intertek.com sau scanând codul din dreapta cu un smartphone. Prezentul certificat este pentru utilizarea exclusivă a clientului AMTAC și este furnizat în conformitate cu acordul dintre AMTAC și Clientul său. Responsabilitatea și răspunderea AMTAC sunt limitate la termenii și condițiile acordului. AMTAC nu își asumă răspunderea față de nicio parte, cu excepția Clientului, conform acordului, pentru nicio pierdere, cheltuielă sau daună cauzată de folosirea prezentului Certificat. Doar Clientul este autorizat să permită copierea și distribuirea prezentului Certificat. Orice utilizare a numelui AMTAC sau a mărcilor sale pentru vânzarea și promovarea materialelor, produselor sau serviciilor testate trebuie aprobată în prealabil în scris de AMTAC.

Prezentul certificat rămâne proprietatea societății Intertek, careia trebuie să îi fie returnat la cerere.

Certificarea este condiționată de păstrarea sistemului organizației în conformitate cu reglementările prevăzute în prezentul certificat și sub rezerva evaluărilor periodice și a respectării cerințelor contractate ale Organismului Notificat.

AMTAC Certification Services Limited este un Organism Notificat în conformitate cu Directiva 93/42/CEE privind dispozitivele medicale, cu numărul de identificare 0473.



LISTA PRODUSELOR PENTRU CERTIFICATUL 171 CE
SMITHS MEDICAL, ASD, INC

Intertek

Unitate de încălzire fluide cu debit mic
Perfuzoare I.V. cu debit mic
Accesorii unitate de încălzire fluide cu debit mic
Unități de încălzire fluide, Debit mare
Echipamente accesorii debit mare
Perfuzoare I.V. cu debit mare, circuit fluid steril
Perfuzoare I.V. cu debit mare, Accesoriu
Irigatoare, de unică folosință
Unități de încălzire fluide cu debit mare cu PEMS (sisteme medicale programabile)
Perfuzoare I.V. cu debit mic pentru unități PEMS
Unități de încălzire convective
Pături de încălzire convective sterile
Pături de încălzire convective nesterile
Accesorii de încălzire convective
Sonde-termometre generale, Esofagiene/rectale 9-12 Francez
Sonde termometre miocardice, Cateter Foley 8 - 30 mm
Sonde termometre, Cateter Foley 8 - 18 Francez
Sonde termometre, Piele, adulți - nou-născuți
Sonde termometre, timpanice; pentru adulți și pediatrie
Stetoscoape esofagiene, 9-24 Fr
Amplificator nor aerosoli
Valvă bypass pentru HME/HCH
Aparat pentru exerciții respiratorii cu flux redus
Spirometre de stimulare
Sistem de terapie cu presiune pozitivă a căilor respiratorii
Sisteme de terapie cu presiune expiratorie pozitivă vibratoare cu sau fără nebulizator de volum mic
Sistem de terapie cu presiune expiratorie pozitivă

Data inițială a certificării: 24 Iulie 1998

Data intrării în vigoare a certificatului: 24 Iulie 2013

Brian Johnson - Semnatar autorizat – *semnătură indescifrabilă*



EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No.**CE 669121****Issued To:**

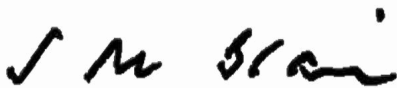
**Smiths Medical ASD Inc.
6000 Nathan Lane North
Minneapolis
Minnesota
55442
USA**

In respect of:

See certificate scope page.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):



Stewart Brain, Head of Compliance & Risk -
Medical Devices

First Issued: **2017-07-20**

Date: **2018-05-09**

Expiry Date: **2023-03-18**

...making excellence a habit.™

Page 1 of 2

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

Certificate No: CE 669121

Certificate Scope:

The design, development and manufacture of:

Sterile Disposable infusion kits including cassette, tubes, connectors, needles

Patient warming units

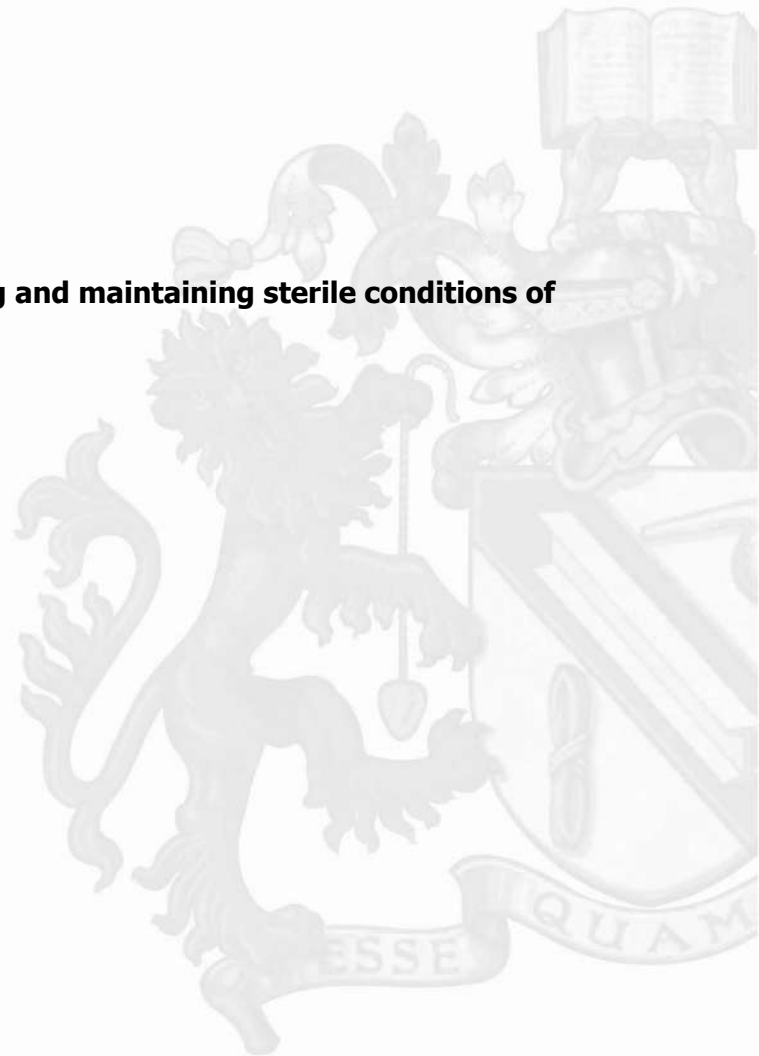
Blood and Fluid Warmers units

Sterile Blood and Fluid Warmers disposables sets

Sterile Central Implantable Access Systems

Sterile Peripheral Implantable Access Systems

Those aspects of Annex II concerned with securing and maintaining sterile conditions of convective warmers blankets.

First Issued: **2017-07-20**Date: **2018-05-09**Expiry Date: **2023-03-18**

...making excellence a habit.™

Page 2 of 2

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 669121**
 Date: **2018-05-09**
 Issued To: **Smiths Medical ASD Inc.
 6000 Nathan Lane North
 Minneapolis
 Minnesota
 55442
 USA**

Subcontractor:	Service(s) supplied
CarTika Medical Inc 6551 Wedgwood Rd N Suite 300 Maple Grove Minnesota 55311 USA	Manufacture
Isomedix Operations, Inc. 380 90th Avenue NW Minneapolis MN 55433 USA	ETO Sterilization
Isomedix Operations, Inc. 7685 Saint Andrews Avenue San Diego California 92154 USA	ETO Sterilization

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 669121**
 Date: **2018-05-09**
 Issued To: **Smiths Medical ASD Inc.
 6000 Nathan Lane North
 Minneapolis
 Minnesota
 55442
 USA**

Subcontractor:	Service(s) supplied
Isomedix Operations, Inc. 43425 Business Park Drive Temecula California 92590 USA	ETO Sterilization
Isomedix Operations, Inc. 23 Elizabeth Drive Chester New York 10918 USA	Gamma Sterilization
Minnetronix, Inc. 1635 Energy Park Drive St Paul Minnesota 55108 USA	Design Manufacture

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 669121**
Date: **2018-05-09**
Issued To: **Smiths Medical ASD Inc.**
6000 Nathan Lane North
Minneapolis
Minnesota
55442
USA

Subcontractor:**Service(s) supplied**

Smiths Healthcare Manufacturing
S.A. de C.V.
Avenida Calidad No. 4
Parque Industrial Internacional
Tijuana
Baja California
22425
Mexico

Manufacture

Smiths Medical ASD Inc.
1265 Grey Fox Road
St Paul
Minnesota
55112
USA

Regulatory Compliance

Smiths Medical ASD, Inc.
3350 Granada Avenue North
Oakdale
Minnesota
55128
USA

Manufacture

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 669121**
 Date: **2018-05-09**
 Issued To: **Smiths Medical ASD Inc.**
6000 Nathan Lane North
Minneapolis
Minnesota
55442
USA

Subcontractor:	Service(s) supplied
Smiths Medical International Limited 1500 Eureka Park Lower Pemberton Ashford Kent TN25 4BF United Kingdom	EU Representative
Sterigenics US, LLC 10811 Withers Cover Park Drive Charlotte North Carolina 28278 USA	ETO Sterilization
Sterigenics US, LLC 1700 College Boulevard West Memphis AR 72301 USA	Gamma Sterilization

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 669121**
 Date: **2018-05-09**
 Issued To: **Smiths Medical ASD Inc.
 6000 Nathan Lane North
 Minneapolis
 Minnesota
 55442
 USA**

Subcontractor:	Service(s) supplied
Sterigenics US, LLC 344 Bonnie Circle Corona California 92880 USA	Gamma Sterilization
Sterigenics US, LLC 7775 South Quincy Willowbrook Illinois 60527 USA	ETO Sterilization
Sterigenics US, LLC 84 Park Road Queensbury New York 12804 USA	ETO Sterilization

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EC Certificate - Full Quality Assurance System

Certificate History

Certificate No: **CE 669121**
Date: **2018-05-09**
Issued To: **Smiths Medical ASD Inc.
6000 Nathan Lane North
Minneapolis
Minnesota
55442
USA**

Date	Reference Number	Action
20 July 2017	8691798	First issue, transferred from another notified body.
Current	8893340	Renewal, scope rewording, scope reduction, subcontractor removal, correction of subcontractor address and activities

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Page 1 of 1

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

Certificat CE – Sistem Complet de Asigurare a Calității

Directiva 93/42/CEE privind Dispozitivele Medicale, Anexa II cu excepția Secțiunii 4

Nr. **CE 669121**
Emis pentru: **Smiths Medical ASD Inc.**
6000 Nathan Lane North
Minneapolis
Minnesota
55442
SUA

Cu privire la:

A se vedea fila cu domeniul de aplicare al certificatului.

pe baza examinării noastre efectuate asupra sistemului de asigurare a calității, în temeiul cerințelor Directivei Consiliului 93/42/CEE, Anexa II cu excepția Secțiunii 4. Sistemul de asigurare a calității întrunește cerințele directivei. Pentru plasarea pe piață a produselor din Clasa III, este necesar un certificat conform Anexei II secțiunea 4.

Pentru și în numele BSI, Organism Notificat pentru Directiva de mai sus (Organism Notificat Numărul 0086):

Semnătură indescifrabilă
Stewart Brain, Director Conformitate & Risc-
Dispozitive Medicale



Prima ediție: **20.07.2017** Data: **09.05.2018**

Data expirării: **18.03.2023**

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Pagina 1 din 2

Valabilitatea acestui certificat este condiționată de menținerea sistemului calității în cerințele Directivei, demonstrate prin activitățile de supraveghere impuse de Organismul Notificat. Această aprobare exclude toate produsele create și/sau fabricate de o parte terță în numele companiei numite în prezentul certificat, dacă nu se agreează în mod specific cu BSI.

Prezentul certificat a fost emis în formă electronică și este supus condițiilor contractului.

Informații și contact: BSI, Kitemark Court, Davy Avenue, Knowhill, Milton Keynes MK5 8PP. Tel: +44 345 080 9000
BSI Assurance UK Limited, înregistrată în Anglia sub numărul 7805321 la 389 Chiswick High Road, Londra W4 4AL,
UK. Membră a Grupului de Companii BSI.

Certificat nr. CE 669121

Domeniul de aplicare al Certificatului:

Proiectarea, dezvoltarea și fabricarea următoarelor produse:

Kit-uri de infuzie sterile, de unica folosinta, inclusiv casete, tuburi, conectori, ace

Unitati de incalzire pacient

Unitati de incalzire sange si fluide

Seturi sterile de unica folosinta incalzire sange si fluide

Sisteme sterile implantabile cu acces central

Sisteme sterile implantabile cu acces periferic

Acele aspecte din Anexa II cu privire la asigurarea și menținerea condițiilor sterile pentru paturici incalzire convectiva.

Prima ediție: **20.07.2017**

Data: **09.05.2017**

Data expirării: **18.03.2023**

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Pagina 2 din 2

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

Valabilitatea acestui certificat este condiționată de menținerea sistemului calității în cerințele Directivei, demonstrate prin activitățile de supraveghere impuse de Organismul Notificat. Această aprobare exclude toate produsele create și/sau fabricate de o parte terță în numele companiei numite în prezentul certificat, dacă nu se agreează în mod specific cu BSI.

Prezentul certificat a fost emis în formă electronică și este supus condițiilor contractului.

Informații și contact: BSI, Kitemark Court, Davy Avenue, Knowhill, Milton Keynes MK5 8PP. Tel: +44 345 080 9000
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UK. Membră a Grupului de Companii BSI.

Certificat CE – Sistem Complet de Asigurare a Calității

Directiva 93/42/CEE privind Dispozitivele Medicale, Anexa II cu excepția Secțiunii 4

Lista principalilor subcontractori

Recunoscuți ca fiind implicați în serviciile legate de produsul acoperit de:

Certificat Nr. **CE 669121**
Data: **09.05.2017**
Emis pentru: **Smiths Medical ASD Inc.**
6000 Nathan Lane North
Minneapolis
Minnesota
55442
SUA

**Subcontractor:****Serviciu(ii) livrat(e)**

CarTika Medical Inc
6551 Wedgwood Rd N
Suite 300
Maple Grove
Minnesota
55311
SUA

Producție

Isomedix Operations Inc.
380 90th Avenue NW
Minneapolis
Minnesota
55433
SUA

Sterilizare ETO

Isomedix Operations Inc.
7685 Saint Andrews Avenue
San Diego
California
92154
SUA

Sterilizare ETO

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Certificat CE – Sistem Complet de Asigurare a Calității

Directiva 93/42/CEE privind Dispozitivele Medicale, Anexa II cu excepția Secțiunii 4

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Emis pentru: **Smiths Medical ASD Inc.**
6000 Nathan Lane North
Minneapolis
Minnesota
55442
SUA



Subcontractor:

Serviciu(ii) livrat(e)

Isomedix Operations Inc.
43425 Business Park Drive
Temecula
California
92590
SUA

Sterilizare ETO

Isomedix Operations Inc.
23 Elizabeth Drive
Chester
New York 10918
SUA

Sterilizare gamma

Minnetronix, Inc.
1635 Energy Park Drive
St Paul
Minnesota
55108
SUA

Proiectare
Producție

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Certificat CE – Sistem Complet de Asigurare a Calității

Directiva 93/42/CEE privind Dispozitivele Medicale, Anexa II cu excepția Secțiunii 4

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Certificat Nr. **CE 669121**
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Emis pentru: **Smiths Medical ASD Inc.**
6000 Nathan Lane North
Minneapolis
Minnesota
55442
SUA



Subcontractor:

Serviciu(ii) livrat(e)

Smiths Healthcare Manufacturing
S.A de C.V.
Avenida Calidad nr. 4
Parque Industrial Internacional
Tijuana
Baja California
22425
Mexic

Producție

Smiths Medical ASD, Inc.
1265 Grey Fox Road
St Paul
Minnesota
55112
SUA

Respectarea reglementarilor

Smiths Medical ASD, Inc.
3350 Granada Ave North
Oakdale
Minnesota
55128
SUA

Producție

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Certificat CE – Sistem Complet de Asigurare a Calității

Directiva 93/42/CEE privind Dispozitivele Medicale, Anexa II cu excepția Secțiunii 4

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Emis pentru: **Smiths Medical ASD Inc.**
6000 Nathan Lane North
Minneapolis
Minnesota
55442
SUA



Subcontractor:

Serviciu(ii) livrat(e)

Smiths Medical International Limited
1500 Eureka Park
Lower Pemberton
Ashford
Kent
TN25 4BF
Regatul Unit

Reprezentanță UE

Sterigenics US, LLC
10811 Withers Cove Park Drive
Charlotte
Carolina de Nord
28278
SUA

Sterilizare ETO

Sterigenics US, LLC
1700 College Blvd
West Memphis
Arkansas
72301
SUA

Sterilizare gamma

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Certificat CE – Sistem Complet de Asigurare a Calității

Directiva 93/42/CEE privind Dispozitivele Medicale, Anexa II cu excepția Secțiunii 4

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Emis pentru: **Smiths Medical ASD Inc.**
6000 Nathan Lane North
Minneapolis
Minnesota
55442
SUA



Subcontractor:

Serviciu(ii) livrat(e)

Sterigenics US, LLC
344 Bonnie Circle
Corona
California
92880
SUA

Sterilizare gamma

Sterigenics US, LLC
7775 South Quincy
Willowbrook
Illinois
60527
SUA

Sterilizare ETO

Sterigenics US, LLC
84 Park Road
Queensbury 12804
New York
SUA

Sterilizare ETO

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Certificat CE – Sistem Complet de Asigurare a Calității

Directiva 93/42/CEE privind Dispozitivele Medicale, Anexa II cu excepția Secțiunii 4

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Emis pentru: **Smiths Medical ASD Inc.**
6000 Nathan Lane North
Minneapolis
Minnesota
55442
SUA



Data	Număr referință	Acțiune
20 iulie 2017	8691798	Prima ediție, transferată de la un alt organism notificat
Curentă	8893340	Reinnoire, reformulare domeniu de aplicare, reducere domeniu de aplicare, eliminare subcontractori, corectie adrese subcontractori si activitati