

Ważna notatka bezpieczeństwa – Implanty Silimed

Nazwa handlowa produktów objętych notatką

Chirurgia plastyczna : Implanty piersi, implanty mięśnia piersiowego, implanty pośladków, implanty łydek, implanty do chirurgii ręki, ekspandery tkanek, implanty twarzy, zaczepty nosowe, podwieszające arkusze do chirurgii piersi

Chirurgia bariatryczna : opaski i balony gastryczne

Implanty do urologii : implanty jąder, implanty prącia, konformery pochwy, zaciski zwieraczy, tuby do spodziectwa, stendy waginalne

Silikonowe implanty do chirurgii ogólnej : bloki i płatki

Silikonowe wyroby inwazyjne : wzorniki do implantów silikonowych

Identyfikator FSCA : FSCA 2015-01

Rodzaj działania : wstrzymanie sprzedaży oraz wystąpienia z prośbą do końcowych odbiorców o wstrzymanie stosowania i wyłączenie ze stosowania wszystkich wymienionych wyrobów.

Data 12.10.2015

Uwaga :

Do wszystkich dystrybutorów i końcowych odbiorców (lekarzy, szpitali i jednostek służby zdrowia)

Szczegóły dotyczące produktów objętych notatką :

Wszystkie partie/ numery seryjne wyrobów wymienionych poniżej :

- **Chirurgia plastyczna** : Implanty piersi, implanty mięśnia piersiowego, implanty pośladków, implanty łydek, implanty do chirurgii ręki, ekspandery tkanek, implanty twarzy, zaczepty nosowe, podwieszające arkusze do chirurgii piersi
- **Chirurgia bariatryczna** : opaski i balony gastryczne
- **Implanty do urologii** : implanty jąder, implanty prącia, konformery pochwy, zaciski zwieraczy, tuby do spodziectwa, stendy waginalne
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Szczegółowa lista wraz z numerami katalogowymi wszystkich produktów stanowi załącznik do niniejszego pisma.

Opis problemu :

Podczas audytu dotyczącego procedur produkcji Silimed przez naszą jednostkę notyfikowaną TUV SUD wykryto cząsteczki na powłoce niektórych implantów piersi. W tym momencie podjęto działania naprawcze w zakresie usunięcia możliwości przeniknięcia cząsteczek na powłokę implantów. Jednakże te działania nie rozwiązały ostatecznie problemu i dlatego TUV SUD zdecydował o wstrzymaniu certyfikatu CE do 17 grudnia 2015.

Aczkolwiek nasza ocena ryzyka nie ujawniła żadnego zagrożenia dla zdrowia, Silimed w rozmowach z właściwymi organami oraz naszą jednostką notyfikowaną postanowił zbadać problem dogłębnie, aby zweryfikować i dostarczyć dowodów, że nie ma żadnego ryzyka dla zdrowia pacjentów i jakie działania zapobiegawcze lub naprawcze, będą konieczne aby wyeliminować przenikanie cząsteczek. **Jako środek zapobiegawczy** końcowi odbiorcy w tym okresie są proszeni o nie wszczepianie wymienionych powyżej wyrobów, aż do odwołania.

Wskazówki w zakresie działań zapobiegawczych, które powinny być podjęte przez użytkownika :

- Wstrzymać implantację i wyłączyć produkty z użytku do odwołania
- Proszę przekazać tę wiadomość do wszystkich pracowników jednostki lub jakiegokolwiek jednostki, gdzie produkty których dotyczy niniejsza nota mogą się znajdować .
- Prosimy o podpisanie załączonego potwierdzenia i odesłanie go do dystrybutora produktów Silimed w celu potwierdzenia otrzymania niniejszej Notatki Bezpieczeństwa. Dane kontaktowe do dystrybutora umieszczono poniżej.

W razie jakichkolwiek pytań prosimy o kontakt :

Dane kontaktowe

Kraj	Adres	Dystrybutor	Osoba do kontaktu	Telefon	e-mail
Polska	Ul. Tęczowa 28E/1 62-064 Plewiska Polska	Beauty-Med.	Łukasz Karczewski	+48 500 243 022	lukasz@beauty- med.com.pl

Niżej podpisany potwierdza że niniejsza Notatka została zgłoszona do właściwych organów.

p/ Louise Azevedo Alves

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CEO

Louise Azevedo Alves
Farmacêutica Responsável
CRF 3417

SILIMED – Industria de Implantes Ltda.
Rua Figueiredo Rocha 374
21240-660 Rio de Janeiro
Brazil

Poniższe potwierdzenie proszę przesłać pocztą elektroniczną na adres lukasz@beauty-med.com.pl lub faxem +48 61 221 69 14

Niżej podpisany potwierdza że otrzymał/a powyższą informację dotyczącą Notatką Bezpieczeństwa o numerze referencyjnym FSCA 2015-01 i zadziała odpowiednio

Nazwa Jednostki

Nazwisko

Data i podpis

List of devices

No.	Device type	Commercial name	Class*	Rule	Catalogue reference number	Short description and intended use
1	Mammary Implant - Silicone Gel	Mammary Implant - Silicone Gel - Smooth Surface	III	2003/12/EC	Please see the Table C5-01-62 R06	<p>Description: Made of a silicone elastomer envelope, with smooth surface. It contains a defined volume of silicone gel.</p> <p>Intended Use: Augmentation aesthetic surgeries, unilateral or bilateral mammary reconstruction and/ or unilateral or bilateral mammary corrections.</p> <p><small>REF.: IUP 001-01-L-EC R04</small></p>
		Mammary Implant - Silicone Gel - Textured Surface				<p>Description: Made a silicone elastomer envelope, with textured surface. It contains a defined volume of silicone gel.</p> <p>Intended Use: Augmentation aesthetic surgeries, unilateral or bilateral mammary reconstruction and/ or unilateral or bilateral mammary corrections.</p> <p><small>REF.: IUP 001-01-T-EC R11</small></p>
		Mammary Implant - Silicone Gel - Polyurethane Foam Coated Surface				<p>Description: Made of a silicone elastomer envelope and polyurethane foam coated. It contains a defined volume of silicone gel.</p> <p>Intended Use: Augmentation aesthetic surgeries, unilateral or bilateral mammary reconstruction and/ or unilateral or bilateral mammary corrections.</p> <p><small>REF.: IUP 001-01-P-E R13</small></p>
		Mammary Implant- Silicone Gel - Irregular Surface				<p>Description: Made of a silicone elastomer envelope, with irregular surface. It contains a defined volume of silicone gel.</p> <p>Intended Use: Plastic surgeries for unilateral or bilateral breast augmentation or reconstruction.</p> <p><small>REF.: IUP 001-01-L-EC R06</small></p>
2	Plastic Surgery – Pectoral Implant	Pectoral Implant – Silicone Gel	I Ib	8	Please see the Table C5-01-61 R09	<p>Description: Made of a silicone elastomer envelope. It contains a defined volume of silicone gel.</p> <p>Intended Use: For cosmetic surgeries, for increase of the projection of the major pectoral muscle; and reconstructive surgeries of the pectoral region.</p> <p><small>REF.: IUP 002-01-LT-EC R03</small></p>
3	Plastic Surgery – Gluteal Implant	Gluteal Implant – Silicone Gel	I Ib	8	Please see the Table C5-01-61 R09	<p>Description: Made of a silicone elastomer envelope (shell). It contains a defined volume of silicone gel.</p> <p>Intended Use: Indicated to provide a natural aesthetic result in augmentation gluteoplasty surgery and uni- or bilateral reconstruction of the gluteal region.</p> <p><small>REF.: IUP 006-01-LP-EC R04</small></p>
4	Plastic Surgery – Implants for Hand Surgery	Tendon Spacer	I Ib	8	Please see the Table C5-01-61 R09	<p>Description: Made of medical-grade silicone elastomer.</p> <p>Intended Use: Indicated for reconstitution of the hand tendons.</p> <p><small>REF.: IUP 013-02-L-EC R03</small></p>

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No.	Device type	Commercial name	Class*	Rule	Catalogue reference number	Short description and intended use
5	Plastic Surgery – Tissue Expanders	Tissue Expander	I Ib	8	Please see the Table C5-01-61 R09	<p>Description: Made of a mechanically resistant silicone elastomer envelope that is smooth or textured, with a valve internally positioned in the envelope (incorporated magnetic valve) or externally connected by a tube and connecting pin (remote valve), through which periodical injections of apyrogenic sterile isotonic saline solution shall be made until the desired expansion is reached.</p> <p>Intended Use: The indications for the expander are multiple, such as breast reconstructions and/or unilateral or bilateral corrections of the breasts, correction of sequelae from burns, baldness surgery, facial tumors, tattoo removal, correction of alopecia, treatment of hairy nevi, correction of malformation of the foot, elongation of the superior oblique tendon for correction of Brown syndrome, reconstruction of the lower / upper limb, reconstruction of head/neck, scalp reconstruction, reconstruction of the atrophic alveolar crest, reconstruction of abdomen, trunk reconstruction, ear reconstruction, correction of the contour of the spine and scars in general.</p> <p><small>REF.: IUP 018-03-LT-EC R12</small></p>
6	Plastic Surgery – Facial Implants	Facial Implant – Chin Implant Facial Implant – Malar Implant Facial Implant – Zygomatic Implant Facial Implant – Implant for Nasal Dorsum Facial Implant – Nasal Implant in “L” Facial Implant – Ear Implant	I Ib	8	Please see the Table C5-01-61 R09	<p>Description: It is made of a mechanically resistant silicone elastomer, with smooth or textured surface.</p> <p>Intended Use: The Facial Implant is indicated for application in aesthetic or reconstructive surgery of the face.</p> <p><small>REF.: IUP 027-02-LT-EC R07</small></p>
7	Plastic Surgery – Nostril Retainer	Nostril Retainer	IIa	5	Please see the Table C5-01-61 R09	<p>Description: Formed by silicone elastomer, with attachments on the right and left sides.</p> <p>Intended Use: Indicated for septoplasty and primary rhinoplasty surgeries.</p> <p><small>REF.: IUP 029-02-L-EC R02.</small></p>
8	Bariatric Surgery – Gastric Balloon	Gastric Balloon	I Ib	5	Please see the Table C5-01-61 R09	<p>Description: It consists of a round fluorated silicone envelope, filling tube, luer-lock and metal guide.</p> <p>Intended Use: indicated for temporary use for up to 6 months.</p> <p>The Gastric Balloon is a non-surgical treatment of obesity that shall be accompanied by a change in the patient’s behavior.</p> <p><small>REF.: IUP 015-03-L-E R06</small></p>

No.	Device type	Commercial name	Class*	Rule	Catalogue reference number	Short description and intended use
9	Urology – Testicular Implant	Testicular Implant – Silicone Gel	IIb	8	Please see the Table C5-01-61 R09	<p>Description: Mde of a mechanically resistant silicone elastomer envelope (shell). It contains a defined volume of silicone gel.</p> <p>Intended Use: Indicated in cases of aesthetic construction and reconstruction surgery to correct conditions such as congenital malformation, traumatisms and testicle disorders.</p> <p><small>REF.: IUP 005-01-L-EC R03</small></p>
		Testicular Implant – Silicone Elastomer				<p>Description: Made of a mechanically resistant silicone elastomer envelope (shell). It contains a defined volume of silicone elastomer.</p> <p>Intended Use: Indicated in cases of aesthetic construction and reconstruction surgery to correct conditions such as congenital malformation, traumatisms and testicle disorders.</p> <p><small>REF.: IUP 005-02-L-EC R03</small></p>
10	Urology – Penile Implant	Penile Implant	IIb	8	Please see the Table C5-01-61 R09	<p>Description: It is made of a proximal extremity, principal body and distal extremity, made of medical-grade silicone and silver core.</p> <p>Intended Use: Indicated for correction of masculine erectile dysfunction.</p> <p><small>REF.: IUP 004-02-C R04</small></p>
11	Urology – Vesical Conformer	Vesical Conformer	IIa	7	Please see the Table C5-01-61 R09	<p>Description: It consists of a balloon connected to a luer with a lid by means of a silicone tube, through which the filling product is introduced.</p> <p>Intended Use: It was devised for the purpose of helping in the early stage of scarring, in the post-operative period of bladder reconstruction.</p> <p><small>REF.: IUP 008-03-L-EC R02</small></p>
12	Urology – Periurethral Constrictor – Inflatable	Periurethral Constrictor Inflatable	IIb	8	Please see the Table C5-01-61 R09	<p>Description: Periurethral Constrictor - Inflatable - Smooth Surface; Periurethral Constrictor - Inflatable - ACUA-D: It is comprised of a constrictor body connected to a valve with a tube.</p> <p>Intended Use: Meant for treatment of slight and moderate to grave sphincter urinary incontinence.</p> <p><small>REF.: IUP 007-03-L-EC R04</small></p>
13	Urology – Tubes for Hypospadias	Tube for Hypospadias	IIa	7	Please see the Table C5-01-61 R09	<p>Description: It consists of a silicone elastomer catheter open at one end and equipped with a sliding surface. The end of the tube has a blunt tip designed not to damage the patient's vesical epithelium.</p> <p>Intended Use: It has been designed for reparatory surgery in cases of patients with hypospadias.</p> <p><small>REF.: IUP 010-02-L-EC R03</small></p>
14	Urology – Vaginal Stent	Vaginal Stent – Inflatable	IIb	8	Please see the Table C5-01-61 R09	<p>Description: Made of a silicone elastomer envelope, connected to a filling tube.</p> <p>Intended Use: Used in surgical or non-surgical reparatory and/or constructive procedures of the vagina.</p> <p><small>REF.: IUP 009-03-L-EC E03</small></p>

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No.	Device type	Commercial name	Class*	Rule	Catalogue reference number	Short description and intended use
15	General Surgery – Silicone Block and Sheet	Silicone Sheet	IIb	8	Please see the Table C5-01-61 R09	<p>Description: Made of silicone elastomer, which is homogeneous, pure or reinforced, translucent and colorless.</p> <p>Intended Use: The Silicone Sheet is a product that, once trimmed by the physician, is intended to replace or augment soft or cartilaginous tissues. Silicone Block, likewise, is a semi-finished product that, once carved by the physician, is intended to replace or augment soft or cartilaginous tissues.</p> <p><small>REF.: IUP 011-02-L-N R03</small></p>
		Silicone Block				
16	Plastic Surgery – Calf Implant	Calf Implant – Silicone Gel	IIb	8	Please see the Table C5-01-61 R09	<p>Description: Made of a silicone elastomer envelope (shell). It contains a defined volume of silicone gel.</p> <p>Intended Use: Augmentation surgeries; and unilateral or bilateral reconstruction of the calf region.</p> <p><small>REF.: IUP 003-01-L-EC R05</small></p>
		Calf Implant – Silicone Elastomer				
17	Silicone Invasive Devices – Sizers for Silicone Implants	Sizer for Silicone Implant (Mammary Implant, Gluteal Implant, Penile Implant, Testicular Implant)	IIa	6	Please see the Table C5-01-61 R09	<p>Description:</p> <p>Sizer for Mammary Implant, Sizer for Gluteal Implant, Sizer for Calf Implant, Sizer for Testicular Implant: Made of a elastomer container with a defined volume of silicone gel or silicone elastomer equivalent to the volume of the corresponding implant.</p> <p>Sizer for Penile Implants: Made silicone elastomer with a graded scale on the surface.</p> <p>Intended Use: Indicated to be used in surgery for placing silicone implants, as a help for the surgeon to evaluate the size of the implant to be used, as well as the size of the implantation pocket, prior to the definitive implantation of the device.</p> <p><small>REF.: IUP 020-01-L-N R05-DR; IUP 043-01-L-E R01; IUP 022-01-L-N R03; IUP 024-01-L-N R01; IUP 023-01-L-N R01; IUP 021-03-L-N R02.</small></p>
18	Plastic Surgery – Suspension Sheet for Mammoplasty	Suspension Sheet for Mammoplasty	IIb	8	Please see the Table C5-01-61 R08	<p>Description: Silicone sheet polyurethane foam-coated surface.</p> <p>Intended Use: To lend internal reinforcement to the breast in surgery to correct ptosis, with or without reduction.</p> <p><small>REF.: IUP 026-02-P-E R03</small></p>
19	Silicone Product for Topical Use	Medgel – Inverted “T” Medgel – Plate Medgel – Strip Medgel – Disks Medgel Coat	I	1	Please see the Table C5-01-61 R09	<p>Description: It is a silicone gel, soft, gently adherent, half occlusive and reinforced. Medgel Coat forms an extremely fine membrane on the skin, similar to an invisible bandage.</p> <p>Intended Use: The Medgel products are intended for the prevention and for treatment of scars, hypertrophic scars and keloid scars.</p> <p><small>REF.: IUP 019-01-L-N R03</small></p>

*The here above product list classification is based on the classification claim of the manufacturer and under its sole responsibility (MDD 93/42/EEC, article 2 & Annex IX; MEDDEV 2.4/1 Rev.9, chapter 3.1 & 3.3)