TECHNICAL BOOKLET
OF LABORATOIRES SEBBIN

SEBBIN PARIS
ESTHETIQUE & RECONSTRUCTION

Recreating harmonious bodies for a new vision of rebirth.

TRUST AND TRANSPARENCY: STRONG VALUES

Recreating harmonious bodies for a new vision of rebirth…

Whether it is a matter of reconstruction or aesthetic enhancement, the aim is always allowing the patient to rediscover harmony in body as well as in mind. With the greatest respect for ethics, of utmost priority today than ever before, it is the desire of the Laboratoires Sebbin, above any other consideration, to optimize permanently the reliability of their implants. Thus they protect the peace of mind of the surgeons and patients. In this booklet, we want to make you know, in total transparency, the technical aspects of our products from the selection of raw materials up to their follow-up after implantation.

Because our business operates in a medical environment, it can be considered only in a context of absolute trust between patient, surgeon and manufacturer. Therefore the Laboratoires SEBBIN put every effort to ensure optimum quality of their products.

THE SEBBIN COMPANY

Since near 30 years, GROUPE SEBBIN SAS is a French company located near Paris. With an international orientation, its activities are the design, development, manufacture and marketing of inert implants made from long term implantable medical grade silicone, for reconstructive, plastic and aesthetic surgery.
The company has ISO 9001 and ISO 13485 certification for medical devices and has incorporated the ISO 14971 standard.

In addition to its range of round, anatomical and inflatable breast implants, the Laboratoires Sebbin offer surgeons specific implant solutions in response to the needs of their patients (testicular, calf, gluteus implants and skin expanders of various shapes). All these products are CE marked (Annex 2).
In some cases of delicate reconstruction, use of computer-aided design even enables Laboratoires Sebbin to produce custom-made implants of high technicity with the 3D technology.

GROUPE SEBBIN SAS supports all innovations for the future in the field of plastic, reconstructive and aesthetic surgery and devotes a large part of its budget on research and development.

ADRESS: ADMINISTRATION

GROUPE SEBBIN SAS
39-43, Parc d'activités des Quatre Vents
95 650 BOISSY L'AILLERIE

Tel. : +33 1 34 42 13 28
Fax : +33 1 34 42 16 88
www.sebbin.com

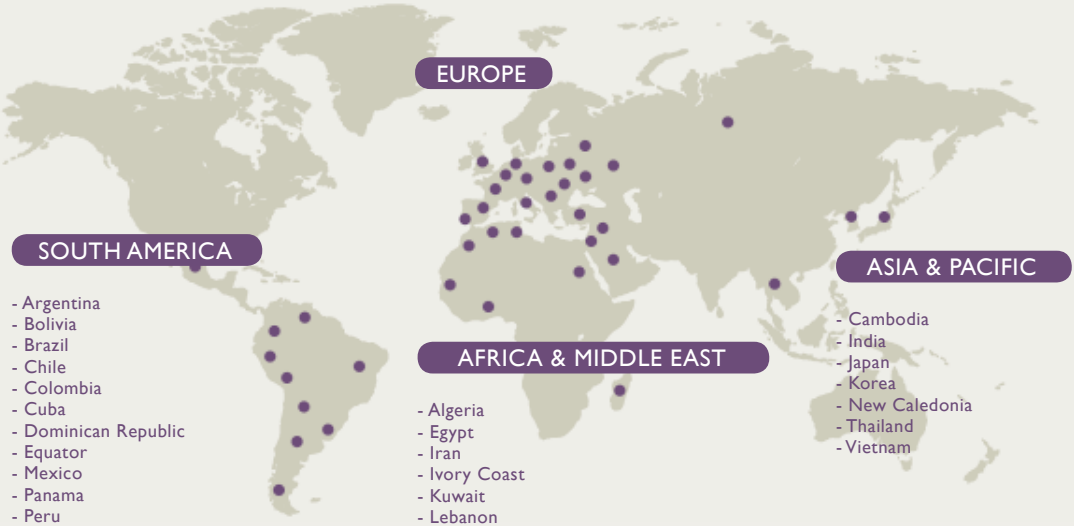
ADRESS: PRODUCTION

GROUPE SEBBIN SAS
39-43, Parc d'activités des Quatre Vents
95 650 BOISSY L'AILLERIE

Tel. : +33 1 34 42 13 28

• INTERNATIONAL PRESENCE.

Laboratoires SEBBIN is present in numerous international markets with a distribution in more than 50 countries:



Global presence at the end of 2012

WHAT IS THE CE MARKING?

One must distinguish the CE marking, which is a mandatory product certification, meaning that the medical device complies with the essential requirements related to safety and performance as per the requirements of the EU directive, from the certification of the company's quality system according to EN ISO 9001 and EN ISO 13485.

Medical devices must be CE marked (European Conformity) by their manufacturer in order to be marketed in Europe. This requirement allows a free circulation of medical devices in all member states of the European Union and the European Economic Area. This is a regulatory framework establishing the technical requirements enforced by all European countries for the design, manufacturing and use of medical device.

According to Directives 93/42/EEC for medical devices and 2003/12/CEE specific classification of breast implants, medical devices are divided into the following four classes: Class I, Class IIa, IIb and III according to the level risk of the device.
Breast implants are in class III because they may represent a critical potential risk. The sizers for breast implants are class IIa because they are surgically invasive devices for temporary use (implanted for less than 60 minutes).

All other medical devices manufactured by the Groupe SEBBIN are class IIb because they are long-term implantable (implanted for more than 30 days).

Breast implants from Groupe SEBBIN are assessed according to the Annex II of the European Directive - Complete quality assurance - including Section 4, the product design review.

The manufacturer must demonstrate compliance of its products with the essential requirements of Directive 93/42/EEC, before being authorized by the notified body to affix the CE mark for the design of a new product or the change of an existing one (change in raw materials, manufacturing processes, shapes ...).

The tasks of the Notified Body are:

- To implement the certification procedures for the issue of the CE mark certificate,
- To evaluate the conformity of the product based on the technical and design file that include:
    - Product Description,
    - Design drawings, manufacturing methods,
    - Risk analysis,
    - List of Standards to comply with,
    - Solutions adopted to meet the essential requirements,
    - Description of methods of sterilization,
    - Tests report and clinical data,
    - Labeling and instructions for use.

- To issue the CE mark certificate,
- To audit the manufacturer each year to check its quality system components and product safety and to ensure it fully complies with current standards.

After gaining the CE mark certificate for a given product, the manufacturer issues a Declaration of Conformity. Doing so, the manufacturer provides clear evidence that its product meets the Essential Requirements of safety and performance of Directive 93/42/EEC and thus formalizes the manufacturer's responsibility to market medical devices compliant with the applicable regulation. For products other than class I, Declaration of Conformity is always linked to the CE certificates issued by the Notified Body.

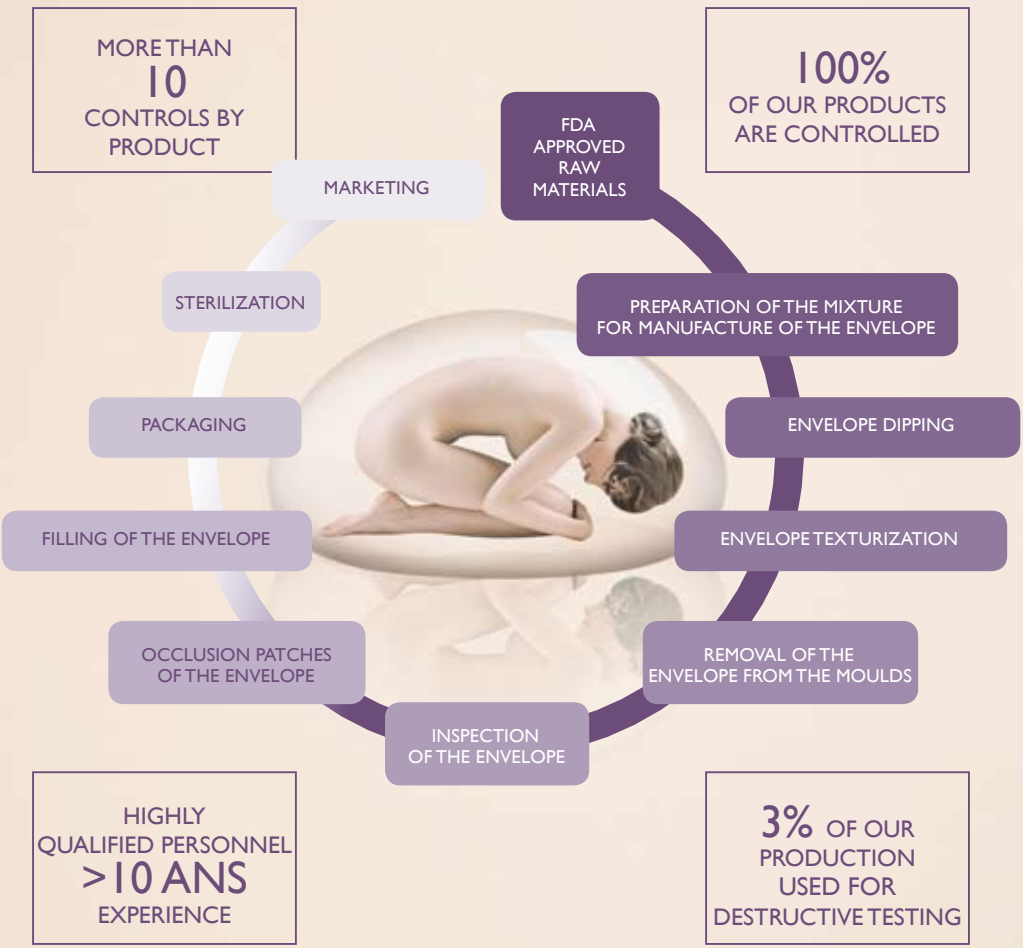
METHOD
OF MANUFACTURE

• THE STAGES OF IMPLANT MANUFACTURE.

Production of implants pre-filled with silicone gel follows a complex manual manufacturing process backed by a modern Enterprise Ressource Planning (ERP) tool, 26 years of know-how, staff professionalism and an efficient Quality System including numerous inspections at all stages of manufacture on every implant.

MORE THAN
10
CONTROLS BY
PRODUCT

100%
OF OUR PRODUCTS
ARE CONTROLLED



HIGHLY
QUALIFIED PERSONNEL
>10 ANS
EXPERIENCE

3% OF OUR
PRODUCTION
USED FOR
DESTRUCTIVE TESTING

THE TESTS

In a constant drive for quality, GROUPE SEBBIN SAS obtains test results that are superior to those of the ISO 14607 standard (the international standard for breast implants).

• DESTRUCTIVE STATISTICAL TESTS CONDUCTED ROUTINELY:

- On 3 % of the production:
  - Elongation test: the apparatus applies traction until the rupture of the sample; it calculates the percentage of elongation until the rupture.
  - Tear resistance test: same test as for the elongation test but the sample is cut on 1mm in order to evaluate the tear resistance of the envelope. There is no specified value requested by the standard.
  - Tensile test: we measure the sample, the apparatus applies traction of 300% during 3mn on the sample and we let it come back to its initial shape. Then, we measure again the sample and this measure mustn't represent more than 10% of the previous one.

- On 0,3 % of the production:
  - Strength of seals: we take a sample including the patch and the envelope and we place it in the apparatus to perform an elongation of 300% during 10 seconds. There mustn't have signs of detachment between the patch and the envelope of the sample.

- On each batch of gel:

  • Penetration of the gel: this test, not required in the standard, is more representative of reality than the cohesion test: it makes it possible to obtain a gel of reproducible quality. It consists of measuring the resistance of the gel to penetration with a constant mass over a given distance, the more the gel resists this penetration, the more it will be called "high cohesive".

• MECHANICAL TESTS RESULTS VS STANDARDS.

TESTS	STANDARD ISO 14607	SEBBIN REFERENCE VALUES
Elongation	≥ 450 %	Average 690 %*
Tear resistance	Not specified	Average 20 kN/m
Tensile set	≤ 10 %	Average 3 %
Strength of seals	Compliance of the bonding after elongation to 300% during 10s	Complies

* Results obtained on the last tests realized by an independant laboratory.

• CONTROLS ACROSS THE ENTIRE PRODUCTION:

- Control of the conductivity for the textured shells.
- Control of the tightness of the envelope.
- Control across 24 points of the shell to ensure a uniform specified thickness.
- Visual controls at each stage of manufacture.

The anti-bleeding barrier for our shells was tested at the time of the CE marking by the LNE, Laboratoire National d'Essais and has been controlled again at the end of 2010 by an independant laboratory.

COMPONENTS
OF THE IMPLANTABLE BREAST PROSTHESES

- RAW MATERIALS.

Any raw material entering into the manufacture of the shell, the digital points, the patch and the gel of these medical devices is of medical quality, biocompatible and implantable at more than 29 days, in conformity with the ISO 14630 and 14607 standards.

Our suppliers of these raw materials are Nusil Technology and Applied Silicone Corporation, the only two manufacturers of long term implantable medical quality silicone, thus biocompatible. This quality is recognized by health authorities all over the world including the French Agence Nationale de Sécurité du Médicament et des produits de santé (ANSM) and the Food and Drug Administration (FDA). Both our suppliers have ISO 9001 certification and exercise rigorous controls over their products (Annex 1).
Further information can be found on the websites:

www.appliedsilicone.com www.nusil.com

- THE SHELL.

The trilaminar shell is made of silicone elastomer. It is obtained by successive dippings of a mould defining the shape, the profile and the volume of the implant, and includes a barrier thus limiting the risk of the gel diffusion.
It complies with the ISO 14607 standard.
Our envelope exists in four surfaces: smooth, micro textured, textured, macro textured, this last one being designed for the anatomical breast implants.

• THE PATCH.

The patch is made of silicone elastomer and includes a barrier limiting the risk of gel diffusion. It comprises the elements making it possible to identify and trace the device – To know more, see chapter on identification and traceability.

• THE FILLING GEL.

The Naturgel™ filling gel is a biocompatible, medical quality, high cohesive silicone gel, implantable at more than 29 days, compatible with its shell and satisfying the ISO 14607 standard. The cohesion / penetration and the filling rate of the gel determine the different families of round mammary implants.

The cohesion of the gel is one of the factors which conditions the consistency of the implant, as also:

- the raw materials used,
- the thickness and softness of the shell,
- the filling rate.

• PACKAGING AND LABELLING.

Each mammary implant comes in a package that meets the ISO 14630 and ISO 11607 standards.
The packaging:

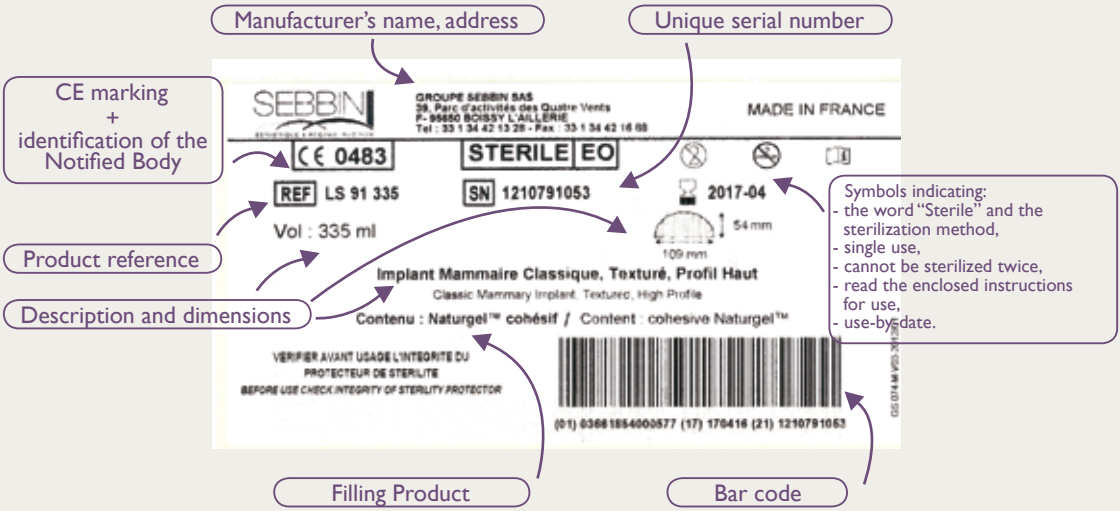
- protects the implant from any damage and deterioration,
- permits the sterilization of the medical device using the sterilization method selected as well as maintains the device sterility during storage and transport.

This package is made of a double blister, placed within a cardboard box.
A pad, turning from burgundy to green in contact with ethylene oxide and glued to a foot of the inner blister, is the witness of the gas contact.

INFORMATION MENTIONED ON THE BOX AND THE BLISTER

An identification label is stuck on the box.

On the operculum of the external blister, is stuck an identification label giving the following information:



The following elements are included into the box:

- a set of 6 stickers

2 under this form

4 under this form

- an implant patient's card on which the identification product sticker for the patient has to be stuck,
- the instructions for use.

The information supplied on our labelling complies with ISO 14630 and NF EN 980 standards. These devices require no accessories in order to be used.

• STERILIZATION METHOD – STORAGE CONDITIONS.

For their medical devices, Laboratoires SEBBIN choose ethylene oxide sterilization because of its efficiency and its common use in medical areas like intra ocular lenses, cochlear implants or heart valve.
Sterilization with ethylene oxide is subcontracted to an ISO 9001, ISO 13485 and ISO 11135 certified establishment.

Each sterilization batch is subjected to:

Before sterilization:
- an evaluation of the initial contamination of the implants or Bioburden: by transfer of the micro-organisms present on the surface of the implant to a culture medium by immersion and successive rinsings in an eluate.

After sterilization:
- checking the biological indicators: by placing in a culture of biological indicators containing at least 10^6 *Bacillus subtilis*.
- measuring the residual ethylene oxide: by gas-phase chromatography with exhaustive extraction by DMF, in accordance with the NF EN ISO 10993-7 standard. The content of the residues from sterilization with ethylene oxide other than ethylene oxide: ethylene glycol and ethylene hydrochloride, have been validated in design.
- search for pyrogenic substances.
- release of a batch by the Quality Manager at the Laboratoires SEBBIN.

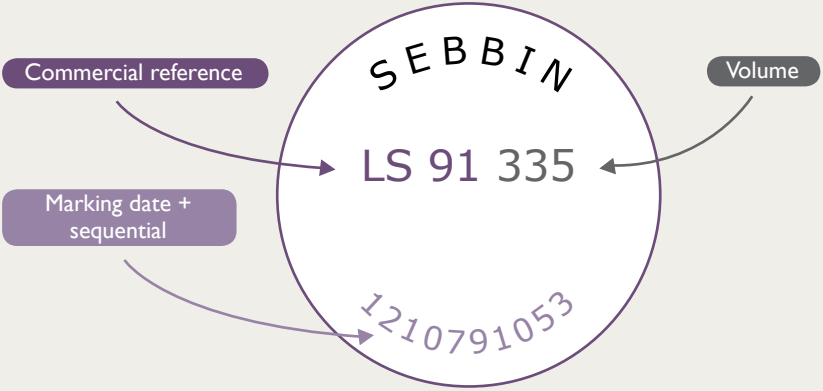
Protected units should be stored flat and protected from water and shocks.

• IDENTIFICATION AND TRACEABILITY.

The implant is identified by the information printed by laser on its patch in the following way:
- its product reference:

- and its unique serial number of 10 figures:

These identification details are found on:
- the labelling,
- and the device patch, as shown below:



The identification system selected is a laser marking system. This marking allows to obtain a legible and non-invasive marking of the patch.

Our traceability system, an integral part of our ISO 9001and ISO 13485 certified quality system and integrating the ISO 14971 standard, allows to recognize and follow the realization of a device from the raw materials delivered by our suppliers until its delivery to the customer, thanks to the unique serial number given to each medical device, inseparably linked to its item reference.

At each stage of their manufacture, the components and/or the devices are subject to various checks and the results of these checks are recorded.

The recordings are classified and archived for a period of 30 years.

QUALITY SYSTEM AND CLINICAL DATA

• QUALITY SYSTEM.

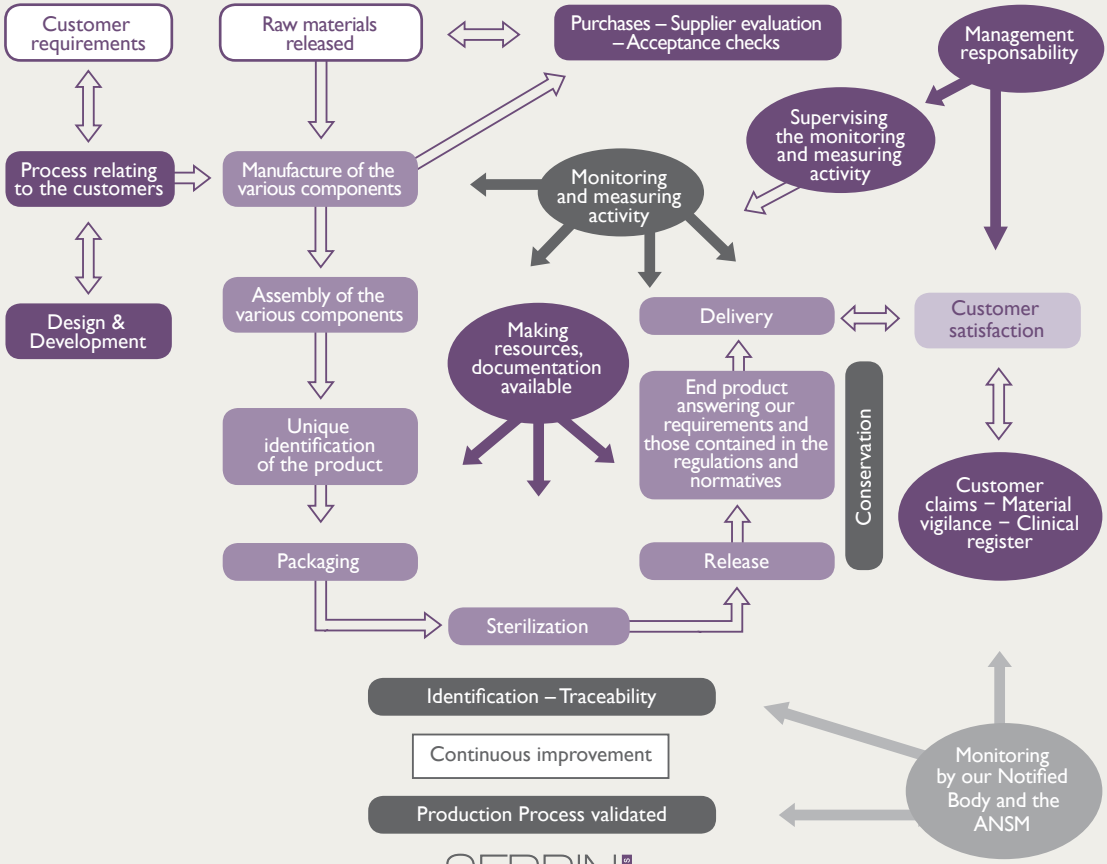
Our company's quality system is NF EN ISO 9001 and NF EN ISO 13485 certified for the development, manufacturing and final inspection of medical devices and incorporates ISO 14971 - Certificates attached in Annex 2.
Attestations certifying the absence of any derivatives of animal origin and of latex type allergens in our products or absence of phtalates are attached in Annex 3.

Controls from various entities may take place in our company:

- At any time, by our government entity, the ANSM, Agence Nationale de Sécurité du Médicament et des dispositifs médicaux (French national agency for the safety of medicine and medical devices).
- At any time, by a foreign government entity as agencies for Health and Safety.
- Every year by our notified body to ensure that we follow the requirements of the 93/42/EEC Directive.
- Every 5 years, by our notified body to renew our certificates of CE.

The customers are informed by the Commercial department of any modification relating to the devices or the Quality System which may have an influence on them; this department is at their disposal for any further information.

FLOW CHART GIVES AN OVERVIEW OF OUR QUALITY SYSTEM:



SEBBIN PARIS
ESTHETIQUE & RECONSTRUCTION

• MATERIOVIGILANCE.

Materiovigilance is monitoring incidents or potential incidents that may result from the use of medical devices after they are on the market. Materiovigilance includes the reporting, recording, evaluation and exploitation of information reported in a goal of prevention.
Laboratoires SEBBIN has established since 2001 a vigilance data base which extracts are given below.

These figures are only indicative as they also take into account implants returned which have been manufactured before 2001.

CUMULATING INCIDENTS FROM 2001 TO 2011 CORRESPONDING TO INTERNATIONAL CLAIMS ON 11 YEARS AND ACCORDING TO THE IMPLANTS SALES DURING THESE 11 YEARS WORLDWIDE.

INTERNATIONAL 2001-2011		
Incident	Implant Pre-filled Textured	Implant Pre-filled Smooth
Intra / extracapsular rupture	< 0,10 %	< 0,06 %
Capsular contracture	< 0,03 %	< 0,02 %
Folds	< 0,01 %	< 0,01 %
Infection/ Lymphorrhoea	< 0,01 %	< 0,01 %

• POST MARKET CLINICAL FOLLOW-UP:

In accordance with the requirements of Directive 93/42/EEC, the Laboratoires Sebbin implemented since 2004 a follow-up of the clinical use (the so called "Post Market Clinical Follow-up" or "PMCF") of its silicone gel pre filled breast implants. This prospective follow-up is carried out in the post marketing phase: it is conducted in 4 centers in France and the intermediate report is related to 256 patients having received breast implants within the scope of breast augmentation for aesthetic or restorative purposes to correct an asymmetry/anomaly (Aesthetic/Plastic Surgery Group) or within the context of breast reconstruction following breast cancer (Reconstructive Surgery Group).

The main objective of this follow-up is to consolidate the data identified at the design stage and check the safety and effectiveness of the Sebbin breast implants prefilled with silicone gel. The rates of implants ruptures and capsular contractures (Baker grade III or IV) were defined as the main criteria of this follow-up.

The intermediate results at 4 years included 256 patients:
- 184 patients were implanted for Aesthetic/Plastic surgery purposes (92.4% with round implants and 7.6% with anatomical implants),
- 72 patients were implanted for Reconstructive surgery purposes (59.7% with round implants and 40.3% with anatomical implants).

The implants used are mainly breast implants with textured surface (91.4% of the patients were implanted with textured breast implants and 8.6% with smooth breast implant).

The 4 years* follow-up generated the following intermediate data versus the above mentioned safety criteria:

		AESTHETIC/PLASTIC SURGERY GROUP (N=184 PATIENTS)	RECONSTRUCTIVE SURGERY GROUP (N=72 PATIENTS)
MAIN COMPLICATIONS	Baker grade III or IV capsular contracture	1,1 % (N=2 patients)	2,8 % (N=2 patients)
	Implant rupture	0 % (N=0 patient)	2,8 % (N=2 patients)

**The follow-up distribution of patients on the 4th of June 2012 is as follows: 9.4% at 3 months, 7.4% at 6 months, 12.5% at 1 year, 16.8% at 2 years, 14.4% at 3 years, 39.5% beyond 3 years.*

The severe capsular contractures rate at 4 years is 1.6% (4 patients out of 256 patients) for the total number of patients who have been implanted: such contractures occurred during the first 9 months after implantation.
In the Aesthetic/Plastic Surgery Group, such rate is at 1.1%. One patient had bilateral capsular contracture which occurred 6 months after implantation and one patient had a unilateral capsular contracture 9 months after implantation.
In the Reconstructive Surgery group, the capsular contractures rate is at 2.8% and those occurred on the 3rd and 4th month following implantation.

The rupture rate is at 0.8% at 4 years (2 patients out of 256 patients) for the total number of patients who have been implanted.
No implant rupture is reported in the Aesthetic/Plastic Surgery Group.
In the Reconstructive Surgery Group the rupture rate is at 2.8%. These two unilateral ruptures occurred on the 44th and 48th month after implantation.

General conclusion:
The 4 years intermediate report data match those generated during the design phase of the Laboratoires Sebbin breast implants. For consolidation purposes of those results, the data collection continues.

ANNEXES

- ANNEX 1: SUPPLIERS ATTESTATION
- ANNEX 2: EC CERTIFICATES
- ANNEX 3: LIABILITY INSURANCE

NuSil SILICONE TECHNOLOGY
Creative Partners in a Material World

December 21, 2011

Sebbin Esthetique & Reconstruction
Diederik Van Goor
39, Parc d'Activites des Quatre Vents
95650 Boissy l'Aillerie, France

Dear Mr. Van Goor,

NuSil Technology's Healthcare product line is differentiated as *unrestricted* or *restricted* materials. Unrestricted materials may be considered for use in long-term human implantation while restricted materials are limited to short-term implantation of 29 days or less or applications outside the human body.

NuSil Technology MED is an unrestricted material. In addition, a Master File for MED has been filed with the U.S. Food and Drug Administration. Authorization to reference the Master File may be obtained by contacting NuSil Technology.

Please note it is the sole responsibility of the user to adequately test and determine the safety and suitability for their application. NuSil Technology makes no warranty concerning fitness for any use or application.

Thank you for your continued interest in NuSil Technology. Should you need any further information on our materials, please do not hesitate to contact us.

Best regards,

S Tschernoscha

Sissy Ann Tschernoscha
Regulatory Affairs

cc : N. Coutin
P. Peignot

NuSil Technology
1050 Cindy Lane • Carpinteria, CA 93013 • 805/684-8780 • 805/566-9905 Fax • www.nusil.com
An ISO 9001 Certified Company

ASC APPLIED SILICONE CORPORATION

270 Quail Court • Santa Paula, CA 93060 • U.S.A.
(805) 525-5657 • (805) 933-1675 Fax
www.appliedsilicone.com

December 16, 2011

To Whom It May Concern:

P.V.P. SAS, formerly known as Laboratories Sebbin, currently purchases and uses the following items as part of their product portfolio:

ASC Part No.	Description
	Dimethyl Silicone Elastomer Dispersion in Xylene
	Responsive Gel System
	HS RTV Elastomer Dispersion in Xylene
	High Strength Firm Silicone Gel System, Low Viscosity
	HS Responsive Silicone Gel, LP, System
	Responsive Gel System, HG
	ALL STANDARD MDM FLUID, MEDICAL GRADE

If you have any questions, please do not hesitate to contact me.

Thank You,

Susan Vicente
Business Operations Manager

Certificate

mdc medical device certification GmbH
certifies that

SEBBIN
ESTHETIQUE & RECONSTRUCTION

GROUPE SEBBIN SAS
39, Parc d'Activités des Quatre Vents
95650 Boissy L'Aillerie
France

for the scope

design, manufacturing and inspection of medical devices made of silicone, including mammary implants and related accessories

has introduced and applies a

Quality Management System

The mdc audit has proven that this quality management system meets all requirements of the following standard

EN ISO 9001

Quality management systems – Requirements

(ISO 9001:2008)

Valid from	2012-01-16
Valid until	2014-07-17
Registration no.	4103.57.11/1
Report no.	E 4103.57 / 2012-01-16
Stuttgart	2012-01-16

Head of Certification Body

medical device certification mdc

DAkkS

mdc medical device certification GmbH
Kriegerstraße 6
D-70191 Stuttgart, Germany
Phone: +49-(0)711-253597-0
Fax: +49-(0)711-253597-10
Internet: http://www.mdc-ce.de

Certificate

mdc medical device certification GmbH
certifies that

SEBBIN
ESTHETIQUE & RECONSTRUCTION

GROUPE SEBBIN SAS
39, Parc d'Activités des Quatre Vents
95650 Boissy L'Aillerie
France

for the scope

design, manufacturing and inspection of medical devices made of silicone, including mammary implants and related accessories

has introduced and applies a

Quality Management System

The mdc audit has proven that this quality management system meets all requirements of the following standard

EN ISO 13485

Medical devices – Quality management systems – Requirements for regulatory purposes

(EN ISO 13485:2003 + AC:2009)

Valid from	2012-01-16
Valid until	2013-07-18
Registration no.	4103.48.11/2
Report no.	E 4103.48 / 2012-01-16
Stuttgart	2012-01-16

Head of Certification Body

medical device certification mdc

Akkreditiert durch

mdc medical device certification GmbH
Kriegerstraße 6
D-70191 Stuttgart, Germany
Phone: +49-(0)711-253597-0
Fax: +49-(0)711-253597-10
Internet: http://www.mdc-ce.de

EC Certificate

mdc medical device certification GmbH
Notified Body 0483
herewith certifies that

SEBBIN
ESTHETIQUE & RECONSTRUCTION

GROUPE SEBBIN SAS
39, Parc d'Activités des Quatre Vents
95650 Boissy L'Aillerie
France

for the scope

gel filled silicone implants (including mammary implants), inflatable silicone implants (including mammary implants), testicular implants, calf implants, gluteal implants, mammary sizers, tissue expanders and filling tubes

has introduced and applies a

Quality System

for the design, manufacture and final inspection.

The mdc audit has proven that this quality system meets all requirements according to

Annex II – excluding Section 4 of the Council Directive 93/42/EEC

of 14 June 1993 concerning medical devices.

The surveillance will be held as specified in Annex II, Section 5.

Valid from	2012-01-16
Valid until	2013-05-27
Registration no.	4103.01.11/2
Report no.	E 4103.01 / 2012-01-16
Stuttgart	2012-01-16

Head of Certification Body

medical device certification mdc

mdc medical device certification GmbH
Kriegerstraße 6
D-70191 Stuttgart, Germany
Phone: +49-(0)711-253597-0
Fax: +49-(0)711-253597-10
Internet: http://www.mdc-ce.de

EC Certificate

mdc medical device certification GmbH
Notified Body 0483
herewith grants

GROUPE SEBBIN SAS
39, Parc d'Activités des Quatre Vents
95650 Boissy L'Aillerie
France

for the scope

gel filled mammary implants:
LS 50, LS 51, LS 52, LS 56, LS 57, LS 70, LS 71, LS 74, LS 90, LS 91, LS 94, LS 95, LS 96, LSC 54, LSC 55, LSC 72, LSC 73, LSC 76, LSC 92, LSC 93, LSA TL, LSA TM, LSA TF, LSA SL, LSA SM, LSA SF

inflatable mammary implants:
LS 20, LS 21

the

EC Design Examination Certificate

The examination of the design of the product by mdc has proven that the design meets the requirements according to

Annex II – Section 4
of the Council Directive 93/42/EEC

of 14 June 1993 concerning medical devices.

This certificate is only valid in connection with a valid mdc certificate according to Annex II – excluding section 4 for the above mentioned products.

Valid from	2012-04-30
Valid until	2013-05-27
Registration no.	4103.11.11/3
Report no.	E 4103.11 / 2012-04-30
Stuttgart	2012-04-30

Head of Certification Body

mdc medical device certification GmbH
Kriegerstraße 6
D-70191 Stuttgart, Germany
Phone: +49-(0)711-253597-0
Fax: +49-(0)711-253597-10
Internet: http://www.mdc-ce.de

EC Certificate

mdc medical device certification GmbH
Notified Body 0483

SEBBIN
ESTHETIQUE & RECONSTRUCTION

GROUPE SEBBIN SAS
39, Parc d'Activités des Quatre Vents
95650 Boissy L'Aillerie
France

for the scope

tubing and other sterile non-invasive accessories for silicone implants

has introduced and applies a

Quality System

for the aspects of manufacture concerned with securing and maintaining sterile conditions as specified in Annex V, Section 3.

The mdc audit has proven that this quality system meets all requirements according to

Annex V – Section 3
of the Council Directive 93/42/EEC

of 14 June 1993 concerning medical devices.

The surveillance will be held as specified in Annex V, Section 4.

Valid from	2012-01-16
Valid until	2013-05-27
Registration no.	4103.07.01/2
Report no.	E 4103.07 / 2012-01-16
Stuttgart	2012-01-16

Head of Certification Body

medical device certification mdc

mdc medical device certification GmbH
Kriegerstraße 6
D-70191 Stuttgart, Germany
Phone: +49-(0)711-253597-0
Fax: +49-(0)711-253597-10
Internet: http://www.mdc-ce.de

Annex 3: Liability insurance

CNA

CNA Insurance Company Limited succursale en France: 37 rue de Liège 75008 Paris

ATTESTATION D'ASSURANCE

POLICY N°:	**FNAMT00089**
UNDERWRITER :	**GROUPE SEBBIN** 39 Parc d'activités des 4 Vents 95 650 BOISSY L'AILLERIE
BROKER :	**AUDIT&RISKSOLUTIONS** 47 rue de Liège 75 008 PARIS
INCEPTION DAY :	**March, 6th 2012**

We the undersigned **CNA Insurance Company Limited**, located 37, rue de Liège - 75008 PARIS, hereby certify that **GROUPE SEBBIN** – 39 Parc d'activités des 4 Vents 95 650 BOISSY L'AILLERIE – has subscribed through our Company an insurance policy **Nb FNAMT00089** which provides Products Liability coverage, subject to the insuring agreements, exclusions, conditions and declarations contained therein and during its effective period

TERRITORIALITY Worldwide excluding USA/Canada

The present certificate is subject to the payment of the premium for the period from March, 6th 2012 to December 31st 2012 included and shall not bind the Insurer over and above terms and limits of the aforementioned policy.
The policy is drawn up in French and the French text will prevail.

Issued in Paris, on February, 29th 2012

On behalf of the Company,

CNA

CNA Insurance Company Limited
37 rue de Liège 75008 PARIS
Tél 01 55 30 60 20
Fax 01 55 30 60 [illegible]
RCS Paris 399 040 [illegible]

www.cnaeurope.com

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