

The ethical values of Laboratories ARION naturally leads our company to express our full support to the patients and families who fear the consequences of the overwhelming surgical events.

We regret this situation and deplore the unfavourable image that it presents to the general public and professionals. This image is justified, but it is also extremely damaging to the entire profession and upstanding laboratories such as ours.

Consequently, Laboratoires ARION wish to reassure the patients and surgeons about the quality of their products.

Since 1994, our company, which is located in the SOPHIA ANTIPOLIS technopole in France, has been developing a full range of breast implants that meet the expectations and physiological characteristics of patients and provide concrete solutions to surgeons' demands.

Since our company's inception, the rigour of our manufacturing process and controls, the quality of our partners and the traceability of our products, have enabled LABORATOIRES ARION to design and produce high-quality implants that are in strict compliance with the European standards and regulations in force.

This quest for innovation and our standards of quality make it possible for our company to ensure the excellence of its various ranges of implants for aesthetic or reconstructive surgery.

Our continued efforts to provide quality implants while preserving the necessary aesthetic results expected by patients, has led our company to use a silicone gel for long-term implants and medical purposes from the international reference *NUSIL TECHNOLOGY* exclusively for our entire silicone gel range.

The burdensome surgical events in recent months confirms the technical choices of our company and reaffirms our quest for high standards in order to continue, in the short and long term, to offer a full range of breast implants in compliance with European standards to surgeons and their patients and concretely respond to the patients' questions and concerns:

- either pre-filled with Silicone gel: Monobloc® - Silicone SoftOne® breast implants
- or, a range that is pre-filled with a biodegradable hydrogel, and is perfectly biocompatible. Our reference range of implants BIO: Monobloc®-Hydrogel CMC, advised as preferential by our laboratory since 1994.

Faced with a situation that is worrisome for patients, Laboratoires ARION puts forward its innovation program, recognised research, and development, high-tech production facilities, extensive testing for quality assurance, as well as a warranty programme, and worldwide monitoring of our implants that ensure the highest quality and safety of our breast implants.

Laboratoires ARION are audited and evaluated by a European notified body to ensure continued compliance of its implants and guarantee the EC certificate.

Strict application of these procedures means that our ARION range of implants are made in a strictly controlled environment to ensure the rigour of our production and the quality of each ARION breast implant.

Laboratoires ARION is eager to provide its professional bodies, as well as AFSSAPS and the Ministry of Health with the most appropriate information for the benefit of patients and their surgeons, and is therefore providing links on its web site to the information sites of the *Agence Française de sécurité sanitaire des produits de Santé* (the French Agency for Safety and Health products) and the *Société Française de Chirurgie Plastique Reconstructrice et Esthétique* (French Society of Plastic Reconstructive and Aesthetic Surgery) .

- <http://www.afssaps.fr/>
- <http://www.plasticiciens.org/>

**Sophia Antipolis, the 09/01/2012**  
**Laboratoires ARION**

*Laboratoires Arion*

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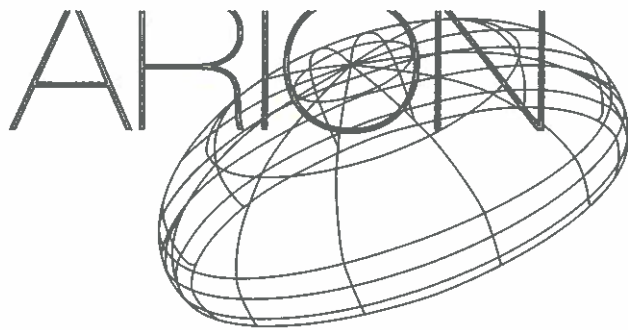
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N° Intracom FR 73 - 398 398 776

SAS au capital de 100 000 €



**CERTIFICATE OF USE OF LONG TERM IMPLANTABLE SILICONE IN THE  
MANUFACTURE OF MONOBLOC® BREAST IMPLANTS**

Laboratoires Arion hereby certify that the materials used in the manufacture of their Monobloc® breast implants are those described in the conception files of CE marked products, the pre-clinical trials (tests of biocompatibility and mechanical tests) were performed on breast implants made from these materials, the results are in conformity with the requirements of references used according to the current regulations.

The silicones used in the manufacture of the Monobloc® breast implants, all references, are in the specifications, with references : SP10, SP15, SP16 signed with the supplier (NUSIL TECHNOLOGY) from the conception and are exclusively medical grade and long-term implantable (unrestricted).

NUSIL TECHNOLOGY manufactures only the highest quality medical-grade silicone materials available domestically and internationally for use of medical implants that are approved by the United States Food and Drug Administration (FDA) and other international regulatory authorities (EC). Master files for the medical grade silicone products are maintained with the FDA and other international regulatory agencies.

Sophia-Antipolis, 11 January 2012

Antonella Coco  
Quality Manager

**LABORATOIRES ARION**

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January 16, 2012

COCO Antonella  
Responsable Qualité  
Laboratoires ARION  
Parc de Haute Technologie  
694 avenue du Dr Donat  
06 250 Mougins - Sophia Antipolis  
France

**Re: NuSil Technology MED3-6300 Silicone Gel**

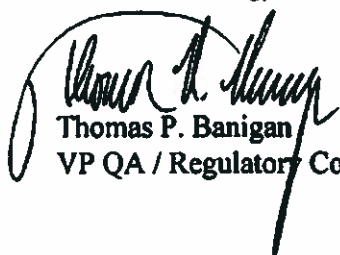
Dear Ms. COCO,

Please be advised that MED3-6300 Silicone Gel, which NuSil Technology supplies to Laboratoires ARION, has been tested for 90-day implantation as well as the other biocompatibility tests listed on Figure 1 (attached). Regarding the technical / regulatory support of this product, a Master File has been submitted to the United States Food & Drug Administration.

Please contact me directly at (805) 566-4125, or [tom@NuSil.com](mailto:tom@NuSil.com) if you require additional information concerning this matter.

Sincerely,

NuSil Technology



Thomas P. Banigan  
VP QA / Regulatory Compliance

c: P. Peignot  
B. Nash

NuSil Technology LLC

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An ISO 9001 Certified Company

(Figure 1)



Creative Partners in a Material World

**Biological Testing Data  
MED3-6300**

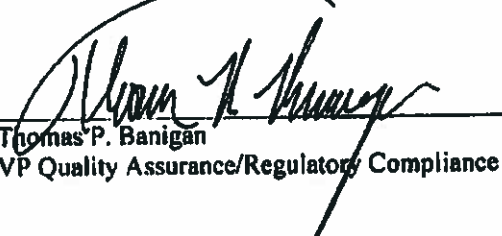
Test	Standard/Method	Test Results
Cytotoxicity Study Using The ISO Elution Method (1X MEM Extract)	ISO 10993-5 USP <87>	A-Noncytotoxic B-Noncytotoxic C-Noncytotoxic
Cytotoxicity Study Using The Agarose Overlay Method (Liquid)	ISO 10993-5 USP <87>	A-Noncytotoxic B-Noncytotoxic C-Noncytotoxic
<i>In Vitro</i> Hemolysis Study (Modified ASTM-Extraction Method)	ISO 10993-4	A-Nonhemolytic
USP and ISO Systemic Toxicity Study Extracts*	ISO 10993-11 USP <88>	A- Nontoxic
ISO Intracutaneous Study Extracts*	ISO 10993-10 USP <88>	A-Slight Irritant
ISO Muscle Implantation Study 1 Week*	ISO 10993-6	A-Nonirritant
ISO Muscle Implantation Study 12 Week	USP <88>	A-Nonirritant
Genotoxicity: Bacterial Reverse Mutation Study	ISO 10993-3	A-Nonmutagenic
USP Pyrogen Study Material Mediated	ISO 10993-11 USP <151>	A-Nonpyrogenic
ISO Maximization Sensitization Study	ISO 10993-10	A-Nonsensitization
Mammalian Mutagenesis Schultz, "Scientific Justification For The Deletion Of Certain Biological Test From The Testing Scheme Proposed In The FDA's 'Guidance for Manufacturers Of Silicone Devices Affected By The Withdrawal Of Dow Coming Silastic Materials.' "	-----	-----
Cytogenic Damage Schultz, "Scientific Justification For The Deletion Of Certain Biological Test From The Testing Scheme Proposed In The FDA's 'Guidance for Manufacturers Of Silicone Devices Affected By The Withdrawal Of Dow Coming Silastic Materials.' "	-----	-----

\* Product meets USP Class VI test requirements.

**Test Article Conditioning**

Sample	Condition
A	Per NuSil Technology Product Specification
B	Condition A + Hot Air Oven 12 Hours @ 200°C
C	Condition A + Autoclave 2 Hours @ 15 psi

This test article has been tested and found compliant with the above requirements. Please contact the NuSil Technology LLC Healthcare Director if you require additional information.

  
Thomas P. Banigan  
VP Quality Assurance/Regulatory Compliance