

## ATTESTATION CE / EC CERTIFICATE

Approbation du Système Complet d'assurance Qualité / Approval of full Quality Assurance System

ANNEXE II excluant le point 4 Directive 93/42/CEE relative aux dispositifs médicaux

ANNEX II excluding section 4 Directive 93/42/EEC concerning medical devices

Pour les dispositifs de classe III, un certificat CE de conception est requis

For class III devices, a EC design certificate is required

Fabricant / Manufacturer

### LABORATOIRES ARION

Parc Haute Technologie, 694 avenue du Dr Maurice-Donat

06250 MOUGINS SOPHIA-ANTIPOLIS FRANCE

Catégorie du(des) dispositif(s) / Device(s) category

Implants mammaires pré-remplis de gel de silicone

*Breast implants silicone gel filled*

Voir détails sur addendum / See attachment for additional information

Le LNE/G-MED atteste qu'à l'examen des résultats figurant dans le rapport référencé P159913, le système d'assurance qualité - pour la conception, la production et le contrôle final - des dispositifs médicaux énumérés ci-dessus est conforme aux exigences de l'annexe II excluant le point 4 de la Directive 93/42/CEE.

LNE/G-MED certifies that, on the basis of the results contained in the file referenced P159913, the quality system - for design, manufacturing, and final inspection - of medical devices listed here above complies with the requirements of the Directive 93/42/EEC, annex II excluding section 4

La validité du présent certificat est soumise à une vérification périodique ou imprévue

The validity of the certificate is subject to periodic or unexpected verification

Début de validité / Effective date : December 22nd, 2017 (included)

Valable jusqu'au / Expiry date : October 11th, 2020 (included)



On behalf of the Certification Director  
Cécile VAUGELADE  
G-MED Certification Division Manager

**Identification des dispositifs / Identification of devices**

<b>Désignation du dispositif / Accessoires marqués CE</b> <i>Designation of device / Accessories CE marked</i>	<b>Réf commerciale du dispositif ou code article</b> <i>Device commercial reference or article code</i>	<b>Classe du DM / MD class</b>
<p>Implants mammaires Monobloc®-Silicone SoftOne®</p> <p><b>Haut Profil (HP) Texturés (T)</b></p> <p><i>Monobloc® Silicone SoftOne® Breast implants</i></p> <p><b>High Profile (HP) Textured (T)</b></p>	GS – HP 095-T	III
	GS – HP 110-T	
	GS – HP 125-T	
	GS – HP 130-T	
	GS – HP 140-T	
	GS – HP 150-T	
	GS – HP 165-T	
	GS – HP 170-T	
	GS – HP 185-T	
	GS – HP 190-T	
	GS – HP 195-T	
	GS – HP 205-T	
	GS – HP 210-T	
	GS – HP 235-T	
	GS – HP 240-T	
	GS – HP 250-T	
	GS – HP 275-T	
	GS – HP 285-T	
	GS – HP 290-T	
	GS – HP 320-T	
GS – HP 330-T		
GS – HP 360-T		
GS – HP 400-T		
GS – HP 430-T		
GS – HP 500-T		
GS – HP 530-T		

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**On behalf of the Certification Director**  
**Cécile VAUGELADE**  
**G-MED Certification Division Manager**

ADD

720 DM 0701-31 rev 5 du 28/07/2015

<b>Désignation du dispositif / Accessoires marqués CE</b> <i>Designation of device / Accessories CE marked</i>	<b>Réf commerciale du dispositif ou code article</b> <i>Device commercial reference or article code</i>	<b>Classe du DM / MD class</b>
<p>Implants mammaires Monobloc®-Silicone SoftOne®</p> <p><b>Haut Profil (HP) Micro texturés (MT)</b></p> <p><i>Monobloc® Silicone SoftOne® Breast implants</i></p> <p><b>High Profile (HP) Micro Textured (MT)</b></p>	GS – HP 085-MT	III
	GS – HP 100-MT	
	GS – HP 115-MT	
	GS – HP 120-MT	
	GS – HP 130-MT	
	GS – HP 140-MT	
	GS – HP 155-MT	
	GS – HP 160-MT	
	GS – HP 175-MT	
	GS – HP 180-MT	
	GS – HP 185-MT	
	GS – HP 195-MT	
	GS – HP 200-MT	
	GS – HP 225-MT	
	GS – HP 230-MT	
	GS – HP 240-MT	
	GS – HP 265-MT	
	GS – HP 275-MT	
	GS – HP 280-MT	
	GS – HP 310-MT	
	GS – HP 320-MT	
GS – HP 350-MT		
GS – HP 390-MT		
GS – HP 420-MT		
GS – HP 490-MT		
GS – HP 520-MT		

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**On behalf of the Certification Director**  
**Cécile VAUGELADE**  
**G-MED Certification Division Manager**

<b>Désignation du dispositif / Accessoires marqués CE</b> <i>Designation of device / Accessories CE marked</i>	<b>Réf commerciale du dispositif ou code article</b> <i>Device commercial reference or article code</i>	<b>Classe du DM / MD class</b>
<b>Implants mammaires Monobloc®-Silicone SoftOne®</b>  <b>Haut Profil (HP) Lisses (L)</b>  <i>Monobloc® Silicone SoftOne® Breast implants</i>  <b>High Profile (HP) Smooth (L)</b>	GS – HP 085-L	III
	GS – HP 100-L	
	GS – HP 115-L	
	GS – HP 120-L	
	GS – HP 130-L	
	GS – HP 140-L	
	GS – HP 155-L	
	GS – HP 160-L	
	GS – HP 175-L	
	GS – HP 180-L	
	GS – HP 185-L	
	GS – HP 195-L	
	GS – HP 200-L	
	GS – HP 225-L	
	GS – HP 230-L	
	GS – HP 240-L	
	GS – HP 265-L	
	GS – HP 275-L	
	GS – HP 280-L	
	GS – HP 310-L	
GS – HP 320-L		
GS – HP 350-L		
GS – HP 390-L		
GS – HP 420-L		
GS – HP 490-L		
GS – HP 520-L		

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<b>Implants mammaires Monobloc®-Silicone SoftOne®</b>  <b>Bas Profil (LP) Texturés (T)</b>  <i>Monobloc® Silicone SoftOne® Breast implants</i>  <b>Low Profile (LP) Textured (T)</b>	GS - LP 125-T	III
	GS - LP 130-T	
	GS - LP 140-T	
	GS - LP 150-T	
	GS - LP 155-T	
	GS - LP 160-T	
	GS - LP 170-T	
	GS - LP 175-T	
	GS - LP 190-T	
	GS - LP 205-T	
	GS - LP 210-T	
	GS - LP 235-T	
	GS - LP 240-T	
	GS - LP 270-T	
	GS - LP 275-T	
	GS - LP 315-T	
	GS - LP 320-T	
	GS - LP 335-T	
GS - LP 395-T		

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**G-MED Certification Division Manager**

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<p>Implants mammaires Monobloc®-Silicone SoftOne®</p> <p><b>Bas Profil (LP) Micro texturés (MT)</b></p> <p><i>Monobloc® Silicone SoftOne® Breast implants</i></p> <p><b>Low Profile (LP) Micro Textured (MT)</b></p>	GS – LP 115-MT	III
	GS – LP 120-MT	
	GS – LP 130-MT	
	GS – LP 140-MT	
	GS – LP 145-MT	
	GS – LP 150-MT	
	GS – LP 160-MT	
	GS – LP 165-MT	
	GS – LP 180-MT	
	GS – LP 195-MT	
	GS – LP 200-MT	
	GS – LP 225-MT	
	GS – LP 230-MT	
	GS – LP 260-MT	
	GS – LP 265-MT	
	GS – LP 305-MT	
	GS – LP 310-MT	
	GS – LP 325-MT	
GS – LP 385-MT		

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<b>Implants mammaires Monobloc®-Silicone SoftOne®</b>  <b>Bas Profil (LP) Lisses (L)</b>  <i>Monobloc® Silicone SoftOne® Breast implants</i>  <b>Low Profile (LP) Smooth (L)</b>	GS – LP 115-L	III
	GS – LP 120-L	
	GS – LP 130-L	
	GS – LP 140-L	
	GS – LP 145-L	
	GS – LP 150-L	
	GS – LP 160-L	
	GS – LP 165-L	
	GS – LP 180-L	
	GS – LP 195-L	
	GS – LP 200-L	
	GS – LP 225-L	
	GS – LP 230-L	
	GS – LP 260-L	
	GS – LP 265-L	
	GS – LP 305-L	
GS – LP 310-L		
GS – LP 325-L		
GS – LP 385-L		

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<b>Implants mammaires Monobloc®-Silicone SoftOne® Profil</b>  <b>Anatomiques (AN)</b> <b>Micro texturés (MT)</b>  <i>Monobloc® Silicone SoftOne® Breast implants</i>  <b>Anatomic (AN)</b> <b>Micro Textured (MT)</b>	GS – AN 125-MT	III
	GS – AN 145-MT	
	GS – AN 165-MT	
	GS – AN 185-MT	
	GS – AN 215-MT	
	GS – AN 235-MT	
	GS – AN 265-MT	
	GS – AN 285-MT	
	GS – AN 335-MT	
	GS – AN 380-MT	
GS – AN 480-MT		

<b>Désignation du dispositif / Accessoires marqués CE</b> <i>Designation of device / Accessories CE marked</i>	<b>Réf commerciale du dispositif ou code article</b> <i>Device commercial reference or article code</i>	<b>Classe du DM / MD class</b>
<b>Implants mammaires Monobloc®-Silicone SoftOne® Profil</b>  <b>Anatomiques (AN)</b> <b>Texturés (T)</b>  <i>Monobloc® Silicone SoftOne® Breast implants</i>  <b>Anatomic (AN)</b> <b>Textured (T)</b>	GS – AN 135-T	III
	GS – AN 155-T	
	GS – AN 175-T	
	GS – AN 195-T	
	GS – AN 225-T	
	GS – AN 245-T	
	GS – AN 295-T	
	GS – AN 345-T	
	GS – AN 390-T	
	GS – AN 490-T	

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<b>Implants mammaires Monobloc®-Silicone SoftOne®</b>  <b>Extra Haut Profil (XP) Texturés (T)</b>  <i>Monobloc® Silicone SoftOne® Breast implants</i>  <b>Extra High Profile (XP) Textured (T)</b>	GS-XP170-T	III
	GS-XP185-T	
	GS-XP230-T	
	GS-XP265-T	
	GS-XP280-T	
	GS-XP300-T	
	GS-XP330-T	
	GS-XP380-T	
	GS-XP425-T	
	GS-XP485-T	
	GS-XP595-T	
	GS-XP695-T	

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Implants mammaires Monobloc®-Silicone SoftOne®  <b>Extra Haut Profil (XP) Micro texturés (MT)</b>  <i>Monobloc® Silicone SoftOne® Breast implants</i>  <b>Extra High Profile (XP) Micro Textured (MT)</b>	GS-XP170-MT	III
	GS-XP185-MT	
	GS-XP230-MT	
	GS-XP265-MT	
	GS-XP280-MT	
	GS-XP300-MT	
	GS-XP330-MT	
	GS-XP380-MT	
	GS-XP425-MT	
	GS-XP485-MT	
	GS-XP595-MT	
GS-XP695-MT		

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Implants mammaires Monobloc®-Silicone SoftOne®  <b>Extra Haut Profil (XP) Lisses (L)</b>  <i>Monobloc® Silicone SoftOne® Breast implants</i>  <b>Extra High Profile (XP) Smooth (L)</b>	GS-XP170-L	III
	GS-XP185-L	
	GS-XP230-L	
	GS-XP265-L	
	GS-XP280-L	
	GS-XP300-L	
	GS-XP330-L	
	GS-XP380-L	
	GS-XP425-L	
	GS-XP485-L	
	GS-XP595-L	
GS-XP695-L		

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Implants mammaires Monobloc®- Silicone SoftOne® <b>Anatomique Haut Profil (AX)</b> <b>Micro texturés (MT)</b>  <i>Monobloc® Silicone SoftOne® Breast implants Anatomic High Profile (AX) Micro Textured (MT)</i>	GS – AX 170-MT	III
	GS – AX 210-MT	
	GS – AX 260-MT	
	GS – AX 320-MT	
	GS – AX 350-MT	
	GS – AX 370-MT	
	GS – AX 390-MT	
	GS – AX 425-MT	
	GS – AX 500-MT	
	GS – AX 535-MT	

Désignation du dispositif / Accessoires marqués CE <i>Designation of device / Accessories CE marked</i>	Réf commerciale du dispositif ou code article <i>Device commercial reference or article code</i>	Classe du DM / MD class
Implants mammaires Monobloc®- Silicone SoftOne® <b>Anatomique Haut Profil (AX)</b> <b>Texturés (T)</b>  <i>Monobloc® Silicone SoftOne® Breast implants Anatomic High Profile (AX) Textured (T)</i>	GS – AX 170-T	III
	GS – AX 210-T	
	GS – AX 260-T	
	GS – AX 320-T	
	GS – AX 350-T	
	GS – AX 370-T	
	GS – AX 390-T	
	GS – AX 425-T	
	GS – AX 500-T	
	GS – AX 535-T	

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Implants mammaires Monobloc®- Silicone SoftOne® <b>Double cohésivité/ Anatomique Profil (A2XH) Micro texturés (MT)</b>  <i>Monobloc® Silicone SoftOne® Breast implants Double cohesivity Anatomic Profile (A2XH) Micro Textured (MT)</i>	GS- A2XH - 220-MT	III
	GS- A2XH - 270-MT	
	GS- A2XH - 290-MT	
	GS- A2XH - 335-MT	
	GS- A2XH - 360-MT	
	GS- A2XH - 405-MT	
	GS- A2XH - 445-MT	
	GS- A2XH - 465-MT	
	GS- A2XH - 515-MT	
	GS- A2XH - 540-MT	
GS-A2XH - 575-MT		
Désignation du dispositif / Accessoires marqués CE <i>Designation of device / Accessories CE marked</i>	Réf commerciale du dispositif ou code article <i>Device commercial reference or article code</i>	Classe du DM / MD class
Implants mammaires Monobloc®- Silicone SoftOne® <b>Double cohésivité Anatomique Profil (A2XH) Texturés (T)</b>  <i>Monobloc® Silicone SoftOne® Breast implants Double cohesivity Anatomic Profile (A2XH) Textured (T)</i>	GS- A2XH - 220-T	III
	GS- A2XH - 270-T	
	GS- A2XH - 290-T	
	GS- A2XH - 335-T	
	GS- A2XH - 360-T	
	GS- A2XH - 405-T	
	GS- A2XH - 445-T	
	GS- A2XH - 465-T	
	GS- A2XH - 515-T	
	GS- A2XH - 540-T	
GS-A2XH - 575-T		

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Implants mammaires Monobloc®- Silicone SoftOne® <b>Double cohésivité Anatomique Profil (A2X) Micro texturés (MT)</b>  <i>Monobloc® Silicone SoftOne® Breast implants Double cohesivity Anatomic Profile (A2X) Micro Textured (MT)</i>	A2X – 195-MT	III
	A2X – 240-MT	
	A2X – 295-MT	
	A2X – 355-MT	
	A2X – 395-MT	
	A2X – 420-MT	
	A2X – 455-MT	
	A2X – 475-MT	
	A2X – 510-MT	
A2X – 540-MT		

Désignation du dispositif / Accessoires marqués CE <i>Designation of device / Accessories CE marked</i>	Réf commerciale du dispositif ou code article <i>Device commercial reference or article code</i>	Classe du DM / MD class
Implants mammaires Monobloc®- Silicone SoftOne® <b>Double cohésivité Anatomique Profil (A2X) texturés (T)</b>  <i>Monobloc® Silicone SoftOne® Breast implants Double cohesivity Anatomic Profile (A2X) Textured (T)</i>	A2X – 195-T	III
	A2X – 240-T	
	A2X – 295-T	
	A2X – 355-T	
	A2X – 395-T	
	A2X – 420-T	
	A2X – 455-T	
	A2X – 475-T	
	A2X – 510-T	
A2X – 540-T		

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Implants mammaires Monobloc®- Silicone SoftOne® <b>Double cohésivité Anatomique Profil (A2XS) Micro Texturés (MT)</b>  <i>Monobloc® Silicone SoftOne® Breast implants Double cohesivity Anatomic Profile (A2XS) Micro Textured (MT)</i>	A2XS – 225-MT	III
	A2XS – 275-MT	
	A2XS – 290-MT	
	A2XS – 330-MT	
	A2XS – 355-MT	
	A2XS – 370-MT	
	A2XS – 410-MT	
	A2XS – 435-MT	
	A2XS – 450-MT	
	A2XS – 470-MT	
	A2XS – 510-MT	
A2XS – 550-MT		

Désignation du dispositif / Accessoires marqués CE <i>Designation of device / Accessories CE marked</i>	Réf commerciale du dispositif ou code article <i>Device commercial reference or article code</i>	Classe du DM / MD class
Implants mammaires Monobloc®- Silicone SoftOne® <b>Double cohésivité Anatomique Profil (A2XS) Texturés (T)</b>  <i>Monobloc® Silicone SoftOne® Breast implants Double cohesivity Anatomic Profile (A2XS) Textured (T)</i>	A2XS – 225-T	III
	A2XS – 275-T	
	A2XS – 290-T	
	A2XS – 330-T	
	A2XS – 355-T	
	A2XS – 370-T	
	A2XS – 410-T	
	A2XS – 435-T	
	A2XS – 450-T	
	A2XS – 470-T	
	A2XS – 510-T	
A2XS – 550-T		

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<b>Implants mammaires Monobloc®-Silicone SoftOne®</b>  <b>Ultra Haut Profil (XXP) Texturés (T)</b>  <i>Monobloc® Silicone SoftOne® Breast implants</i>  <b>Ultra-High Profile (XXP) Textured (T)</b>	GS-XXP265-T	III
	GS-XXP300-T	
	GS-XXP340-T	
	GS-XXP360-T	
	GS-XXP395-T	
	GS-XXP410-T	
	GS-XXP440-T	
	GS-XXP475-T	
	GS-XXP500-T	
	GS-XXP530-T	
	GS-XXP560-T	
	GS-XXP600-T	
GS-XXP650-T		

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<b>Implants mammaires Monobloc®-Silicone SoftOne®</b>  <b>Ultra Haut Profil (XXP) Micro Texturés (MT)</b>  <i>Monobloc® Silicone SoftOne® Breast implants</i>  <b>Ultra-High Profile (XXP) Micro Textured (MT)</b>	GS-XXP265-MT	III
	GS-XXP300-MT	
	GS-XXP340-MT	
	GS-XXP360-MT	
	GS-XXP395-MT	
	GS-XXP410-MT	
	GS-XXP440-MT	
	GS-XXP475-MT	
	GS-XXP500-MT	
	GS-XXP530-MT	
	GS-XXP560-MT	
	GS-XXP600-MT	
GS-XXP650-MT		

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<b>Implants mammaires Monobloc®-Silicone SoftOne®</b>  <b>Ultra Haut Profil (XXP) Lisses (L)</b>  <i>Monobloc® Silicone SoftOne® Breast implants</i>  <b>Ultra-High Profile (XXP) Smooth (L)</b>	GS-XXP265-L	III
	GS-XXP300-L	
	GS-XXP340-L	
	GS-XXP360-L	
	GS-XXP395-L	
	GS-XXP410-L	
	GS-XXP440-L	
	GS-XXP475-L	
	GS-XXP500-L	
	GS-XXP530-L	
	GS-XXP560-L	
	GS-XXP600-L	
	GS-XXP650-L	

**Ce certificat couvre le site et les activités suivants**  
*This certificate covers the following site and activities*

- LABORATOIRES ARION - Parc Haute Technologie, 694 avenue du Dr Maurice Donat, 06250 MOUGINS SOPHIA-ANTIPOLIS FRANCE**  
**Siège social – Activités de conception, fabrication et contrôle final / Headquarter – Design, manufacturing and final inspection activities**

<b>LNE/G-MED</b>	<b>0459</b>
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**On behalf of the Certification Director**  
**Cécile VAUGELADE**  
**G-MED Certification Division Manager**