

EC Design-Examination Certificate

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

№ 01713

No.

CE 645522

Issued To:

Eurosilicone SAS
Z.I de La Peyrolière
B.P. 68
APT Cédex
84402
France

In respect of:

Silicone gel pre-filled mammary implants.

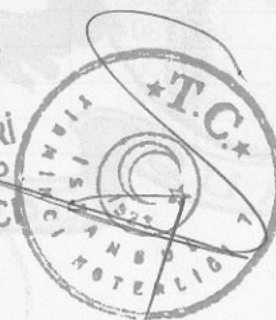
BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4. The design conforms to the requirements of this directive. For marketing of these products an additional Annex II excluding Section 4 certificate is required.

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



Frank Lee, EMEA Compliance & Risk Director

İSTANBUL 20. NOTERİ
İMZA YETKİLİ KATİP
SERHAN MANDACI



First Issued: **05 August 2016**

Date: **16 September 2016**

Expiry Date: **10 November 2018**

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

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
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Supplementary Information to CE 645522

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Round Paragel Mammary Implants, Low Profile, Soft Cohesive Gel Subfamily E.S. 26

Reference	Volume CC	Reference	Volume CC	Reference	Volume CC
26/100	100	26/220	220	26/350	350
26/120	120	26/240	240	26/375	375
26/140	140	26/260	260	26/400	400
26/160	160	26/280	280	26/450	450
26/180	180	26/300	300	26/500	500
26/200	200	26/325	325	-	-

Round Paragel Mammary Implants, Medium Profile, Soft Cohesive Gel Subfamily E.S. 261

Reference	Volume CC	Reference	Volume CC	Reference	Volume CC
261/100	100	261/260	260	261/500	500
261/120	120	261/280	280	261/550	550
261/140	140	261/300	300	261/600	600
261/160	160	261/325	325	261/650	650
261/180	180	261/350	350	261/700	700
261/200	200	261/375	375	261/750	750
261/220	220	261/400	400	261/800	800
261/240	240	261/450	450	-	-

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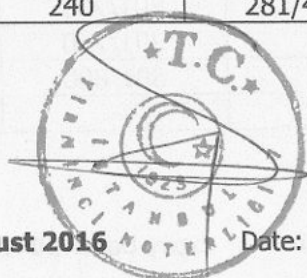
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Round Paragel Mammary Implants, High Profile, Soft Cohesive Gel Subfamily E.S. 28

Reference	Volume CC	Reference	Volume CC	Reference	Volume CC
28/100	100	28/220	220	28/350	350
28/120	120	28/240	240	28/375	375
28/140	140	28/260	260	28/400	400
28/160	160	28/280	280	28/450	450
28/180	180	28/300	300	28/500	500
28/200	200	28/325	325	-	-

Round Paragel Mammary Implants, Extra High Profile, Soft Cohesive Gel Subfamily E.S. 281

Reference	Volume CC	Reference	Volume CC	Reference	Volume CC
281/100	100	281/260	260	281/500	500
281/120	120	281/280	280	281/550	550
281/140	140	281/300	300	281/600	600
281/160	160	281/325	325	281/650	650
281/180	180	281/350	350	281/700	700
281/200	200	281/375	375	281/750	750
281/220	220	281/400	400	281/800	800
281/240	240	281/450	450	-	-



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Round Cristalline Paragel Mammary Implants, Low Profile, Soft Cohesive Gel Subfamily E.S. 80

Reference	Volume CC	Reference	Volume CC	Reference	Volume CC
80/060	60	80/200	200	80/350	350
80/080	80	80/220	220	80/375	375
80/100	100	80/240	240	80/400	400
80/120	120	80/260	260	80/450	450
80/140	140	80/280	280	80/500	500
80/160	160	80/300	300	-	-
80/180	180	80/325	325	-	-

Round Cristalline Paragel Mammary Implants, Medium Profile, Soft Cohesive Gel Subfamily E.S. 801

Reference	Volume CC	Reference	Volume CC	Reference	Volume CC
801/100	100	801/260	260	801/500	500
801/120	120	801/280	280	801/550	550
801/140	140	801/300	300	801/600	600
801/160	160	801/325	325	801/650	650
801/180	180	801/350	350	801/700	700
801/200	200	801/375	375	801/750	750
801/220	220	801/400	400	801/800	800
801/240	240	801/450	450	-	-

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Round Cristalline Paragel Mammary Implants, High Profile, Soft Cohesive Gel Subfamily E.S. 81

Reference	Volume CC	Reference	Volume CC	Reference	Volume CC
81/060	60	81/200	200	81/350	350
81/080	80	81/220	220	81/375	375
81/100	100	81/240	240	81/400	400
81/120	120	81/260	260	81/450	450
81/140	140	81/280	280	81/500	500
81/160	160	81/300	300	-	-
81/180	180	81/325	325	-	-

Round Cristalline Paragel Mammary Implants, Extra High Profile, Soft Cohesive Gel Subfamily E.S. 811

Reference	Volume CC	Reference	Volume CC	Reference	Volume CC
811/100	100	811/260	260	811/500	500
811/120	120	811/280	280	811/550	550
811/140	140	811/300	300	811/600	600
811/160	160	811/325	325	811/650	650
811/180	180	811/350	350	811/700	700
811/200	200	811/375	375	811/750	750
811/220	220	811/400	400	811/800	800
811/240	240	811/450	450	-	-

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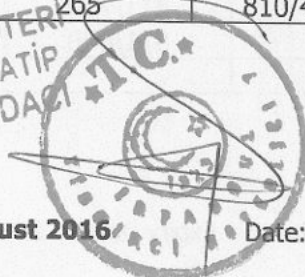
**Round Cristalline Paragel Mammary Implants, Medium Profile, Natural Cohesive Gel Subfamily
E.S. 802N**

Reference	Volume CC	Reference	Volume CC	Reference	Volume CC
802/100N	100	802/260N	260	802/500N	500
802/120N	120	802/280N	280	802/550N	550
802/140N	140	802/300N	300	802/600N	600
802/160N	160	802/325N	325	802/650N	650
802/180N	180	802/350N	350	802/700N	700
802/200N	200	802/375N	375	802/750N	750
802/220N	220	802/400N	400	802/800N	800
802/240N	240	802/450N	450	-	-

**Round Cristalline Paragel Mammary Implants, High Profile, Natural Cohesive Gel Subfamily
E.S. 810N**

Reference	Volume CC	Reference	Volume CC	Reference	Volume CC
810/155N	155	810/295N	295	810/500N	500
810/180N	180	810/320N	320	810/665N	665
810/215N	215	810/350N	350	810/765N	765
810/240N	240	810/390N	390	-	-
810/265N	265	810/435N	435	-	-

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Round Cristalline Paragel Mammary Implants, Medium Extra High Profile, Natural Cohesive Gel Subfamily E.S. 805N

Reference	Volume CC	Reference	Volume CC	Reference	Volume CC
805/170N	170	805/290N	290	805/420N	420
805/195N	195	805/310N	310	805/450N	450
805/215N	215	805/335N	335	805/480N	480
805/240N	240	805/360N	360	-	-
805/265N	265	805/390N	390	-	-

Round Cristalline Paragel Mammary Implants, Extra High Profile, Natural Cohesive Gel Subfamily E.S. 812N

Reference	Volume CC	Reference	Volume CC	Reference	Volume CC
812/100N	100	812/260N	260	812/500N	500
812/120N	120	812/280N	280	812/550N	550
812/140N	140	812/300N	300	812/600N	600
812/160N	160	812/325N	325	812/650N	650
812/180N	180	812/350N	350	812/700N	700
812/200N	200	812/375N	375	812/750N	750
812/220N	220	812/400N	400	812/800N	800
812/240N	240	812/450N	450	-	-



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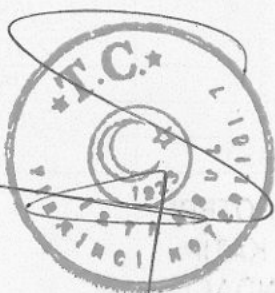
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**Anatomic Cristalline Paragel Mammary Implants, High Profile, Natural Cohesive Gel Subfamily
The Matrix – Full**

Reference	Volume CC	Reference	Volume CC	Reference	Volume CC
TMF1/120	120	TMF2/150	150	TMF3/175	175
TMF1/140	140	TMF2/175	175	TMF3/205	205
TMF1/170	170	TMF2/195	195	TMF3/230	230
TMF1/195	195	TMF2/225	225	TMF3/275	275
TMF1/225	225	TMF2/250	250	TMF3/305	305
TMF1/250	250	TMF2/285	285	TMF3/345	345
TMF1/290	290	TMF2/320	320	TMF3/385	385
TMF1/320	320	TMF2/360	360	TMF3/430	430
TMF1/370	370	TMF2/410	410	TMF3/475	475
TMF1/420	420	TMF2/465	465	TMF3/545	545
-	-	TMF2/540	540	TMF3/610	610
-	-	TMF2/615	615	TMF3/680	680
-	-	TMF2/670	670	TMF3/730	730

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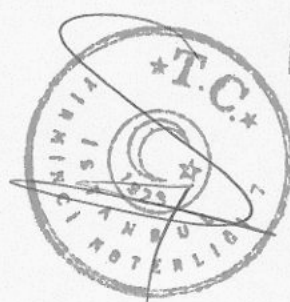
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Anatomic Cristalline Paragel Mammary Implants, High Profile, Natural Cohesive Gel Subfamily
The Matrix – Medium

Reference	Volume CC	Reference	Volume CC	Reference	Volume CC
TMM1/110	110	TMM2/140	140	TMM3/160	160
TMM1/125	125	TMM2/160	160	TMM3/190	190
TMM1/145	145	TMM2/180	180	TMM3/215	215
TMM1/175	175	TMM2/210	210	TMM3/255	255
TMM1/195	195	TMM2/235	235	TMM3/290	290
TMM1/225	225	TMM2/270	270	TMM3/320	320
TMM1/255	255	TMM2/305	305	TMM3/370	370
TMM1/295	295	TMM2/350	350	TMM3/410	410
TMM1/330	330	TMM2/385	385	TMM3/445	445
TMM1/375	375	TMM2/435	435	TMM3/515	515
-	-	TMM2/495	495	TMM3/575	575
-	-	TMM2/560	560	TMM3/645	645
-	-	TMM2/615	615	TMM3/695	695



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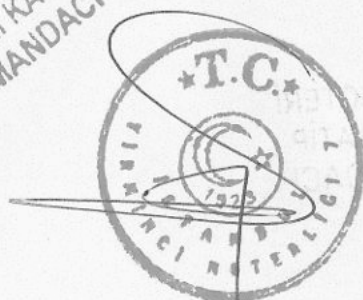
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**Anatomic Cristalline Paragel Mammary Implants, High Profile, Natural Cohesive Gel Subfamily
The Matrix – Low**

Reference	Volume CC	Reference	Volume CC	Reference	Volume CC
TML1/100	100	TML2/120	120	TML3/145	145
TML1/115	115	TML2/145	145	TML3/175	175
TML1/130	130	TML2/175	175	TML3/200	200
TML1/160	160	TML2/195	195	TML3/240	240
TML1/180	180	TML2/225	225	TML3/270	270
TML1/210	210	TML2/260	260	TML3/310	310
TML1/245	245	TML2/295	295	TML3/360	360
TML1/280	280	TML2/330	330	TML3/390	390
TML1/320	320	TML2/375	375	TML3/450	450
TML1/355	355	TML2/415	415	TML3/495	495

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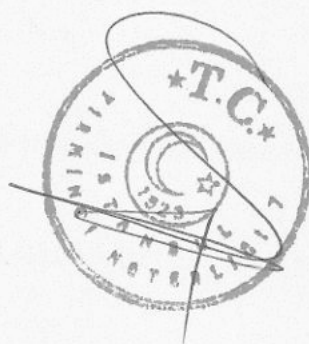
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Certificate History

Date	Reference Number	Action
05 August 2016	10159692	First issue. Transfer from another Notified Body.
16 September 2016	10163266	Review of Tyvek packaging change.



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