



Certificate No. 7389-9-2015

CERTIFICATE TO FOREIGN GOVERNMENT

In order to allow the importation of United States products into foreign countries, the U.S. Food and Drug Administration (FDA) certifies the following information concerning the product(s) to be exported listed below:

Name of Product(s)

See Attached List

(11 Pages)

Name of Manufacturer/Distributor, Address

Name of Manufacturer

MENTOR

3041 SKYWAY CIRCLE NORTH

IRVING, TX USA 75038

The product(s) described above (and the manufacturing/distribution site(s) which produces/distributes it) is subject to the jurisdiction of the FDA under the Federal Food, Drug, and Cosmetic Act.

It is certified that the above product(s) may be marketed in, and legally exported from, the United States of America at this time. The manufacturing plant(s) in which the product(s) is produced is subject to periodic inspections. The last such inspection showed that the plant(s), at that time, appeared to be in substantial compliance with current good manufacturing practice requirements for the product(s) listed above.

Carl Fischer, Ph.D.  
Director  
Division of International Compliance Operations  
Office of Compliance  
Center for Devices and Radiological Health

This certificate is valid from September 17, 2015 to September 16, 2017.





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Name of Manufacturer

MENTOR

3041 SKYWAY CIRCLE NORTH  
IRVING, TX USA 75038

Name of Product(s)

Smooth Round Spectrum® Post-Operatively Adjustable Saline Breast Implant

Catalog No.	Size
350-1410	125 cc
350-1420	175 cc
350-1430	225 cc
350-1440	275 cc
350-1450	325 cc
350-1460	375 cc
350-1470	425 cc
350-1480	475 cc
350-1485	525 cc
350-1490	575 cc

Smooth Round Moderate Profile Saline Breast Implant with Diaphragm Valve

Catalog No.	Size
350-1610	125 cc
350-1615	150 cc
350-1620	175 cc
350-1625	200 cc
350-1630	225 cc
350-1635	250 cc
350-1640	275 cc
350-1645	300 cc
350-1650	325 cc
350-1655	350 cc
350-1660	375 cc
350-1670	425 cc
350-1680	475 cc
350-1685	525 cc
350-1690	575 cc
350-1695	625 cc
350-1697	700 cc

Smooth Round Moderate Plus Profile Saline Breast Implant with Diaphragm Valve

Catalog No.	Size
350-2175	175 cc
350-2200	200 cc
350-2225	225 cc
350-2250	250 cc
350-2275	275 cc
350-2300	300 cc
350-2325	325 cc
350-2350	350 cc
350-2375	375 cc
350-2400	400 cc
350-2425	425 cc
350-2450	450 cc
350-2475	475 cc
350-2500	500 cc
350-2550	550 cc
350-2600	600 cc
350-2650	650 cc





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350-2700	700 cc
350-2750	750 cc
350-2800	800 cc

Smooth Round High Profile Saline Breast Implant with Diaphragm Valve

Catalog No.	Size
350-3170	170 cc
350-3190	190 cc
350-3210	210 cc
350-3230	230 cc
350-3250	250 cc
350-3270	270 cc
350-3290	290 cc
350-3310	310 cc
350-3330	330 cc
350-3380	380 cc
350-3420	420 cc
350-3460	460 cc
350-3500	500 cc
350-3560	560 cc
350-3630	630 cc

Siltex™ Spectrum® Post-Operatively Adjustable Saline Breast Implant

Catalog No.	Size
354-2410M	125 cc
354-2420M	175 cc
354-2430M	225 cc
354-2440M	275 cc
354-2450M	325 cc
354-2460M	375 cc
354-2470M	425 cc
354-2480M	475 cc
354-2511	275 cc
354-2512	350 cc
354-2513	450 cc
354-2514	550 cc
354-2515	650 cc

350-DOMPK Injection Domes with Stainless Steel & True-Lock Connection Systems

Siltex™ Round Moderate Profile Saline Breast Implant with Diaphragm Valve

Catalog No.	Size
354-2610	125 cc
354-2615	150 cc
354-2620	175 cc
354-2625	200 cc
354-2630	225 cc
354-2635	250 cc
354-2640	275 cc
354-2645	300 cc
354-2650	325 cc
354-2655	350 cc
354-2660	375 cc
354-2670	425 cc
354-2680	475 cc

Siltex™ Contour Profile™ Saline Breast Implant with Diaphragm Valve

Catalog No.	Size
354-2711	275 cc





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354-2712	350 cc
354-2713	450 cc
354-2714	550 cc
354-2715	650 cc
354-2910	175 cc
354-2911	225 cc
354-2912	275 cc
354-2913	350 cc
354-2914	425 cc
354-2915	525 cc
600975-001	Mentor Diaphragm Valve - Fill Tube

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**Smooth Round Moderate Plus Profile Gel-Filled Breast Implants**

Catalog No.	Size
350-1001BC	100 cc
350-1251BC	125 cc
350-1501BC	150 cc
350-1751BC	175 cc
350-2001BC	200 cc
350-2251BC	225 cc
350-2501BC	250 cc
350-2751BC	275 cc
350-3001BC	300 cc
350-3251BC	325 cc
350-3501BC	350 cc
350-3751BC	375 cc
350-4001BC	400 cc
350-4251BC	425 cc
350-4501BC	450 cc
350-4751BC	475 cc
350-5001BC	500 cc
350-5251BC	525 cc
350-5501BC	550 cc
350-5751BC	575 cc
350-6001BC	600 cc
350-6501BC	650 cc
350-7001BC	700 cc
350-7501BC	750 cc
350-8001BC	800 cc

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**Smooth Round High Profile Gel-Filled Breast Implants.**

Catalog No.	Size
350-1254BC	125 cc
350-1504BC	150 cc
350-1754BC	175 cc
350-2004BC	200 cc
350-2254BC	225 cc
350-2504BC	250 cc
350-2754BC	275 cc
350-3004BC	300 cc
350-3254BC	325 cc
350-3504BC	350 cc
350-3754BC	375 cc
350-4004BC	400 cc
350-4254BC	425 cc
350-4504BC	450 cc
350-4754BC	475 cc
350-5004BC	500 cc





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350-5504BC	550 cc
350-6004BC	600 cc
350-6504BC	650 cc
350-7004BC	700 cc
350-7504BC	750 cc
350-8004BC	800 cc

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**Smooth Round Moderate Profile Gel-Filled Breast Implants**

Catalog No.	Size
350-7100BC	100 cc
350-7125BC	125 cc
350-7150BC	150 cc
350-7175BC	175 cc
350-7200BC	200 cc
350-7225BC	225 cc
350-7250BC	250 cc
350-7275BC	275 cc
350-7300BC	300 cc
350-7325BC	325 cc
350-7350BC	350 cc
350-7375BC	375 cc
350-7400BC	400 cc
350-7450BC	450 cc
350-7500BC	500 cc
350-7550BC	550 cc
350-7600BC	600 cc
350-7700BC	700 cc
350-7800BC	800 cc

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**Smooth Round Moderate Classic Profile Gel-Filled Breast Implants**

Catalog No.	Size
350-7130MC	130 cc
350-7150MC	150 cc
350-7170MC	170 cc
350-7190MC	190 cc
350-7215MC	215 cc
350-7235MC	235 cc
350-7255MC	255 cc
350-7275MC	275 cc
350-7300MC	300 cc
350-7320MC	320 cc
350-7340MC	340 cc
350-7360MC	360 cc
350-7385MC	385 cc
350-7405MC	405 cc
350-7425MC	425 cc
350-7445MC	445 cc
350-7470MC	470 cc
350-7490MC	490 cc
350-7510MC	510 cc
350-7555MC	555 cc
350-7595MC	595 cc
350-7640MC	640 cc
350-7680MC	680 cc
350-7750MC	750 cc
350-7800MC	800 cc

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**Smooth Round Ultra High Profile Silicone Gel-Filled Breast Implant**





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Catalog No.	Size
350-5135BC	135 cc
350-5160BC	160 cc
350-5185BC	185 cc
350-5215BC	215 cc
350-5240BC	240 cc
350-5270BC	270 cc
350-5295BC	295 cc
350-5320BC	320 cc
350-5350BC	350 cc
350-5375BC	375 cc
350-5400BC	400 cc
350-5430BC	430 cc
350-5455BC	455 cc
350-5480BC	480 cc
350-5535BC	535 cc
350-5590BC	590 cc

Siltex™ Round Moderate Plus Profile Gel-Filled Breast Implants

Catalog No.	Size
354-1001	100 cc
354-1251	125 cc
354-1501	150 cc
354-1751	175 cc
354-2001	200 cc
354-2251	225 cc
354-2501	250 cc
354-2751	275 cc
354-3001	300 cc
354-3251	325 cc
354-3501	350 cc
354-3751	375 cc
354-4001	400 cc
354-4251	425 cc
354-4501	450 cc
354-4751	475 cc
354-5001	500 cc
354-5251	525 cc
354-5501	550 cc
354-5751	575 cc
354-6001	600 cc
354-6501	650 cc
354-7001	700 cc
354-7501	750 cc
354-8001	800 cc

Siltex™ Round Moderate Profile Gel-Filled Breast Implants

Catalog No.	Size
354-1007	100 cc
354-1257	125 cc
354-1507	150 cc
354-1757	175 cc
354-2007	200 cc
354-2257	225 cc
354-2507	250 cc
354-2757	275 cc
354-3007	300 cc
354-3257	325 cc







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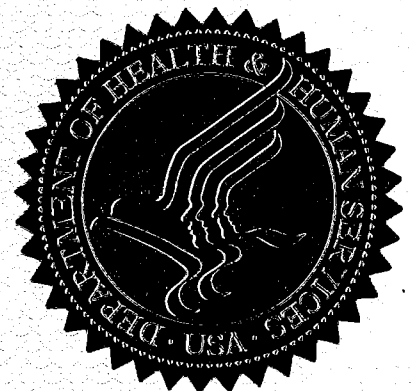
354-3507	350 cc
354-3757	375 cc
354-4007	400 cc
354-4507	450 cc
354-5007	500 cc
354-5507	550 cc
354-6007	600 cc
354-7007	700 cc
354-8007	800 cc

**Siltex™ Round High Profile Gel-Filled Breast Implants**

Catalog No.	Size
354-4125	125 cc
354-4150	150 cc
354-4175	175 cc
354-4200	200 cc
354-4225	225 cc
354-4250	250 cc
354-4275	275 cc
354-4300	300 cc
354-4325	325 cc
354-4350	350 cc
354-4375	375 cc
354-4400	400 cc
354-4425	425 cc
354-4450	450 cc
354-4475	475 cc
354-4500	500 cc
354-4550	550 cc
354-4600	600 cc
354-4650	650 cc
354-4700	700 cc
354-4750	750 cc
354-4800	800 cc

**Siltex™ Round Moderate Classic Profile Gel-Filled Breast Implants**

Catalog No.	Size
354-1307MC	130 cc
354-1507MC	150 cc
354-1707MC	170 cc
354-1907MC	190 cc
354-2157MC	215 cc
354-2357MC	235 cc
354-2557MC	255 cc
354-2757MC	275 cc
354-3007MC	300 cc
354-3207MC	320 cc
354-3407MC	340 cc
354-3607MC	360 cc
354-3857MC	385 cc
354-4057MC	405 cc
354-4257MC	425 cc
354-4457MC	445 cc
354-4707MC	470 cc
354-4907MC	490 cc
354-5107MC	510 cc
354-5557MC	555 cc
354-5957MC	595 cc





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354-6407MC 640 cc  
354-6807MC 680 cc  
354-7507MC 750 cc  
354-8007MC 800 cc

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**Siltex™ Round Ultra High Profile Silicone Gel-Filled Breast Implant**

Catalog No.	Size
354-5135	135 cc
354-5160	160 cc
354-5185	185 cc
354-5215	215 cc
345-5240	240 cc
354-5270	270 cc
354-5295	295 cc
354-5320	320 cc
354-5350	350 cc
354-5375	375 cc
354-5400	400 cc
354-5430	430 cc
354-5455	455 cc
354-5480	480 cc
354-5535	535 cc

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**Single Use Saline Breast Implant Sizer - Round Moderate Profile**

Catalog No.	Size
351-125SZ	125 cc
351-175SZ	175 cc
351-225SZ	225 cc
351-275SZ	275 cc
351-325SZ	325 cc
351-375SZ	375 cc
351-425SZ	425 cc
351-475SZ	475 cc

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**Single Use Saline Breast Implant Sizer - Contour Profile**

Catalog No.	Size
351-0711SZ	275 cc
351-0712SZ	350 cc
351-0713SZ	450 cc
351-0714SZ	550 cc
351-0715SZ	650 cc

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**Single Use Saline Breast Implant Sizer - Round, Moderate Plus Profile**

Catalog No.	Size
351-2175SZ	175 cc
351-2200SZ	200 cc
351-2225SZ	225 cc
351-2250SZ	250 cc
351-2275SZ	275 cc
351-2300SZ	300 cc
351-2325SZ	325 cc
351-2350SZ	350 cc
351-2375SZ	375 cc
351-2400SZ	400 cc
351-2425SZ	425 cc
351-2450SZ	450 cc
351-2475SZ	475 cc
351-2500SZ	500 cc







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351-2550SZ	550 cc
351-2600SZ	600 cc
351-2650SZ	650 cc
351-2700SZ	700 cc
351-2750SZ	750 cc
351-2800SZ	800 cc

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**Single Use Saline Breast Implant Sizer - Round, High Profile**

Catalog No.	Size
351-3190SZ	190 cc
351-3230SZ	230 cc
351-3270SZ	270 cc
351-3290SZ	290 cc
351-3310SZ	310 cc
351-3330SZ	330 cc
351-3380SZ	380 cc
351-3420SZ	420 cc
351-3500SZ	500 cc
351-3630SZ	630 cc

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**MemoryGel Resterilizable Gel Sizer Moderate Classic Profile**

Catalog No.	Size
RSZ-7130MCS	130 cc
RSZ-7150MCS	150 cc
RSZ-7170MCS	170 cc
RSZ-7190MCS	190 cc
RSZ-7215MCS	215 cc
RSZ-7235MCS	235 cc
RSZ-7255MCS	255 cc
RSZ-7275MCS	275 cc
RSZ-7300MCS	300 cc
RSZ-7320MCS	320 cc
RSZ-7340MCS	340 cc
RSZ-7360MCS	360 cc
RSZ-7385MCS	385 cc
RSZ-7405MCS	405 cc
RSZ-7425MCS	425 cc
RSZ-7445MCS	445 cc
RSZ-7470MCS	470 cc
RSZ-7490MCS	490 cc
RSZ-7510MCS	510 cc
RSZ-7555MCS	555 cc
RSZ-7595MCS	595 cc
RSZ-7640MCS	640 cc
RSZ-7680MCS	680 cc
RSZ-7750MCS	750 cc
RSZ-7800MCS	800 cc

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**MemoryGel Resterilizable Gel Sizer High Profile**

Catalog No.	Size
RSZ-1254S	125 cc
RSZ-1504S	150 cc
RSZ-1754S	175 cc
RSZ-2004S	200 cc
RSZ-2254S	225 cc
RSZ-2504S	250 cc
RSZ-2754S	275 cc
RSZ-3004S	300 cc





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RSZ-3254S	325 cc
RSZ-3504S	350 cc
RSZ-3754S	375 cc
RSZ-4004S	400 cc
RSZ-4254S	425 cc
RSZ-4504S	450 cc
RSZ-4754S	475 cc
RSZ-5004S	500 cc
RSZ-5504S	550 cc
RSZ-6004S	600 cc
RSZ-6504S	650 cc
RSZ-7004S	700 cc
RSZ-7504S	750 cc
RSZ-8004S	800 cc

MemoryGel Resterilizable Gel Sizer Ultra High Profile

Catalog No.	Size
RSZ-5135S	135 cc
RSZ-5160S	160 cc
RSZ-5185S	185 cc
RSZ-5215S	215 cc
RSZ-5240S	240 cc
RSZ-5270S	270 cc
RSZ-5295S	295 cc
RSZ-5320S	320 cc
RSZ-5350S	350 cc
RSZ-5375S	375 cc
RSZ-5400S	400 cc
RSZ-5430S	430 cc
RSZ-5455S	455 cc
RSZ-5480S	480 cc
RSZ-5535S	535 cc
RSZ-5590S	590 cc

Port Detector/Locator, Aseptic Fluid Transfer System

Catalog No.	
350-4402	Centerscope® Magnetic Detection Device
350-8400	Aseptic Fluid Transfer Sets

Smooth Tissue Expander with Remote Injection Dome

Catalog No.	Size
350-4301M	100 cc
350-4302M	250 cc
350-4303M	400 cc
350-4309M	50 cc
350-4310M	550 cc
350-4311M	700 cc
350-4304M	700 cc
350-4305M	400 cc
350-4306M	1000 cc
350-4307M	550 cc
350-4308M	850 cc
350-4312M	50 cc
350-4313M	100 cc
350-4314M	200 cc
350-4315M	300 cc
350-4316M	400 cc
350-4317M	500 cc





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350-5301M	25 cc
350-5302M	50 cc
350-5303M	75 cc
350-5304M	150 cc
350-5305M	250 cc
350-5306M	125 cc

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**Siltex™ Contour Profile® Breast Tissue Expander with Integral Injection Site**

Catalog No.	Size
354-6111	250 cc
354-6112	350 cc
354-6113	450 cc
354-6114	550 cc
354-6115	650 cc
354-6116	750 cc
354-6211	275 cc
354-6212	350 cc
354-6213	450 cc
354-6214	550 cc
354-6215	650 cc
354-6216	800 cc
354-6311	250 cc
354-6311	250 cc
354-6312	350 cc
354-6313	450 cc
354-6314	550 cc
354-6315	650 cc
354-6316	750 cc
354-6317	850 cc

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**CPX3™ Siltex™ Contour Profile® Breast Tissue Expander with Suturing Tabs**

Catalog No.	Size
354-7111	250 cc
354-7112	350 cc
354-7113	450 cc
354-7114	550 cc
354-7115	650 cc
354-7116	750 cc
354-7211	275 cc
354-7212	350 cc
354-7213	450 cc
354-7214	550 cc
354-7215	650 cc
354-7216	800 cc
354-7311	250 cc
354-7312	350 cc
354-7313	450 cc
354-7314	550 cc
354-7315	650 cc
354-7316	750 cc
354-7317	850 cc

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**CPX™4 Breast Tissue Expander, Textured, Integral Injection Dome**

Catalog No.	Size
354-8111	250 cc
354-8112	350 cc
354-8113	450 cc
354-8114	550 cc





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354-8115	650 cc
354-8116	750 cc
354-8211	275 cc
354-8212	350 cc
354-8213	450 cc
354-8214	550 cc
354-8215	650 cc
354-8216	800 cc
354-8311	250 cc
354-8312	350 cc
354-8313	450 cc
354-8314	550 cc
354-8315	650 cc
354-8316	750 cc
354-8317	850 cc
354-9111	250 cc
354-9112	350 cc
354-9113	450 cc
354-9114	550 cc
354-9115	650 cc
354-9116	750 cc
354-9211	275 cc
354-9212	350 cc
354-9213	450 cc
354-9214	550 cc
354-9215	650 cc
354-9216	800 cc
354-9311	250 cc
354-9312	350 cc
354-9313	450 cc
354-9314	550 cc
354-9315	650 cc
354-9316	750 cc
354-9317	850 cc

-----END OF PRODUCT LIST-----

