EC Certificate

mdc medical device certification GmbH

Notified Body 0483 herewith grants

Polytech Health & Aesthetics GmbH Altheimer Straße 32 64807 Dieburg Germany

for the scope

Mammary implants of a silicone shell with smooth (POLYsmoooth™), textured (MESMOsensitive® or POLYtxt®) and micro-polyurethane (Microthane®) coated surface, single lumen, filled with one or two silicone gels (volumes between 40 ml and 750 ml) (see attachment)

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
 2018-11-27

 Valid until
 2023-11-26

 Registration no.
 D1007400032

 Report no.
 P18-00829-123148

 Stuttgart
 2018-11-23

Head of Certification Body





Internet: http://www.mdc-ce.de

Product category	Product			Class
Mammary implants of a silicone she				
smooth (POLYsmooth™), textured (N	MESMOsensitive®	or POLYtxt®) and		
micro-polyurethane (Microthane®) coa	ated surface, single	e lumen, filled with	one silicone gel	
Modular System				
Même,				
round form, round base, silicone gel f				
smooth surface (POLYsmcoth™)	Profile	REF	Volume [ml]	
	Low	10624-xxx	50 - 440	
	Moderate	10625-xxx	65 - 600	
	High	10626-xxx	80 - 690	
	Extra High	10627-xxx	95 - 685	
textured surface (MESMOsensitive®)	Profile	REF	Volume [ml]	
	Low	15624-xxx	50 - 440	
	Moderate	15625-xxx	65 - 600	
	High	15626-xxx	80 - 690	
	Extra High	15627-xxx	95 - 685	
textured surface (POLYtxt®)	Profile	REF	Volume [ml]	
,	Low	20624-xxx	50 - 440	
	Moderate	20625-xxx	65 - 600	
	High	20626-xxx	80 - 690	
	Extra High	20627-xxx	95 - 685	1
micro-polyurethane foam coated	Profile	REF	Volume [ml]	
surface (Microthane®)	Low	30624-xxx	50 - 440	
	Moderate	30625-xxx	65 - 600	III
	High	30626-xxx	80 - 690	
	Extra High	30627-xxx	95 - 685	
Mammary implants of a silicone she	ll with			1
Mammary implants of a silicone she textured (MESMOsensitive® or POLY	txt [®]) and micro-pol	yurethane (Microth	ane [®]) coated	
surface, single lumen, filled with one	silicone gel	,		
Modular System				
Replicon,				
anatomical form, round base, silicone				
textured surface (MESMOsensitive®)	Profile	REF	Volume [ml]	
	Low	15634-xxx	45 - 385	
	Moderate	15635-xxx	60 - 525	
	High	15636-xxx	70 - 670	
	Extra High	15637-xxx	85 - 735	
textured surface (POLYtxt®)	Profile	REF	Volume [ml]	
	Low	20634-xxx	45 - 385	
	Moderate	20635-xxx	60 - 525	
	High	20636-xxx	70 - 670	
	Extra High	20637-xxx	85 - 735	
micro-polyurethane foam coated				
surface (Microthane®)	Low	30634-xxx	45 - 385	
	Moderate	30635-xxx	60 - 525	
	High	30636-xxx	70 - 670	
	Extra High	30637-xxx	85 - 735	7



Product category	Product			Class
Mammary implants of a silicone she	ll with			
textured (MESMOsensitive® or POLY		olyurethane (Micro	thane [®]) coated	
surface, single lumen, filled with one	silicone gel			
Modular System				
Opticon,				
anatomical form, horizontally oval bas				
textured surface (MESMOsensitive®)	Profile	REF	Volume [ml]	
	Low	15644-xxx	40 - 325	
	Moderate	15645-xxx	50 - 445	
	High	15646-xxx	60 - 560	
	Extra High	15647-xxx	70 - 680	
textured surface (POLYtxt®)	Profile	REF	Volume [ml]	
	Low	20644-xxx	40 - 325	
	Moderate	20645-xxx	50 - 445	
	High	20646-xxx	60 - 560	
	Extra High	20647-xxx	70 - 680	
micro-polyurethane foam coated	Profile	REF	Volume [ml]	
surface (Microthane®)	Low	30644-xxx	40 - 325	
,	Moderate	30645-xxx	50 - 445	
	High	30646-xxx	60 - 560	
	Extra High	30647-xxx	70 - 680]
textured (MESMOsensitive® or POLY surface, single lumen, filled with one simple surface, single lumen, filled with one simple surface, single lumen, filled with one simple surface, single surface, surf	silicone gel		,	
textured surface (MESMOsensitive®)	Profile	REF	Volume [ml]	
textured surface (MESIMOSerisitive)	Low	15674-xxx	55 - 450	
	Moderate	15675-xxx	70 - 610	
	High	15676-xxx	85 - 705	
	Extra High	15677-xxx	100 - 700	
textured surface (POLYtxt®)	Profile	REF	Volume [ml]	
lexidied surface (i OETIXI)	Low	20674-xxx	55 - 450	
	Moderate	20675-xxx	70 - 610	
	High	20676-xxx	85 - 705	
	Extra High	20677-xxx	100 - 700	
micro-polyurethane foam coated	Profile	REF	Volume [ml]	
surface (Microthane®)	Low	30674-xxx	55 - 450	1
Carrage (Microtifation)	Moderate	30675-xxx	70 - 610	┪
	High	30676-xxx	85 - 705	
	Extra High	30677-xxx	100 - 700	
	LEXITATINGIT	100011 XXX	100 700	



Product category	Product			Class
Mammary implants of a silicone she	ll with			
smooth (POLYsmooth™), textured (N	/IESMOsensitive®	or POLYtxt [®]) and		
micro-polyurethane (Microthane®) coa	ated surface, single	e lumen, filled with	one silicone gel	
Sublime Line				
Même,				
round form, round base, silicone gel f				
smooth surface (POLYsmcoth™)	Profile	REF	Volume [ml]	
	Low	10724-xxx	55 - 485	
	Moderate	10725-xxx	70 - 660	
	High	10726-xxx	90 - 690	
	Extra High	10727-xxx	105 - 685	
textured surface (MESMOsensitive®)	Profile	REF	Volume [ml]	
	Low	15724-xxx	55 - 485	
	Moderate	15725-xxx	70 - 660	
	High	15726-xxx	90 - 690	
	Extra High	15727-xxx	105 - 675	
textured surface (POLYtxt®)	Profile	REF	Volume [ml]	
	Low	20724-xxx	55 - 485	
	Moderate	20725-xxx	70 - 660	
	High	20726-xxx	90 - 690	
	Extra High	20727-xxx	105 - 675	
micro-polyurethane foam coated	Profile	REF	Volume [ml]	
surface (Microthane®)	Low	30724-xxx	55 - 485	
	Moderate	30725-xxx	70 - 660	III
	High	30726-xxx	90 - 690	
	Extra High	30727-xxx	105 - 675	
Mammary implants of a silicone she textured (MESMOsensitive® or POLY surface, single lumen, filled with one sublime Line Replicon, anatomical form, round base, silicone	txt [®]) and micro-po	,	,	
textured surface (MESMOsensitive®)	Profile	REF	Volume [ml]	
Total ou during (MEDINIOGONISHIVO)	Low	15734-xxx	50 - 425	1
	Moderate	15735-xxx	65 - 580	1
	High	15736-xxx	75 - 735	1
	Extra High	15737-xxx	95 - 730	
textured surface (POLYtxt®)	Profile	REF	Volume [ml]	
,	Low	20734-xxx	50 - 425	
	Moderate	20735-xxx	65 - 580	
	High	20736-xxx	75 - 735	1
	Extra High	20737-xxx	95 - 730	1
micro-polyurethane foam coated	Profile	REF	Volume [ml]	1
surface (Microthane®)	Low	30734-xxx	50 - 425	1
,	Moderate	30735-xxx	65 - 580	1
	High	30736-xxx	75 - 735	1
	Extra High	30737-xxx	95 - 730	1



Mammary implants of a silicone shell with textured (MESMOsensitive® or POLYtxt®) and micro-polyurethane (Microthane®) coated surface, single lumen, filled with one silicone gel	Product category	Product			Class
surface, single lumen, filled with one silicone gel Sublime Line Opticon, anatomical form, horizontally oval base, silicone gel filled, cohesive, dimensionally stable textured surface (MESMOsensitive) Profile REF Volume [ml] Low 15744-xxx 45 - 360 Moderate 15745-xxx 55 - 490 High 15745-xxx 55 - 490 High 15747-xxx 75 - 750 Forfile REF Volume [ml] Low 20745-xxx 45 - 360 Moderate 20745-xxx 55 - 490 High 20745-xxx 55 - 615 Extra High 20745-xxx 55 - 690 High 20745-xxx 55 - 615 Extra High 20745-xxx 55 - 490 High 1574-xxx 45 - 360 Moderate Moderate 20745-xxx 55 - 615 Extra High 2074-xxx	Mammary implants of a silicone she	ll with			
Sublime Line			olyurethane (Micro	othane®) coated	
Dopticon, anatomical form, horizontally oval base, silicone gel filled, cohesive, dimensionally stable textured surface (MESMOsensitive®) Profile REF Volume [ml] Low 15744-xxx 45 - 360 Moderate 15745-xxx 55 - 490 High 15746-xxx 65 - 615 Extra High 15746-xxx 45 - 360 Moderate 20745-xxx 55 - 640 High 20744-xxx 45 - 360 Moderate 20745-xxx 55 - 490 High 20744-xxx 45 - 360 Moderate 20745-xxx 55 - 490 High 20746-xxx 65 - 615 Extra High 20747-xxx 75 - 750 Profile REF Volume [ml] Low 30744-xxx 45 - 360 Moderate 30745-xxx 55 - 490 High 30746-xxx 65 - 615 Extra High 30746-xxx 65 - 615 Extra High 30746-xxx 65 - 615 Extra High 30747-xxx 75 - 750 Moderate 30745-xxx 55 - 490 High 30746-xxx 65 - 615 Extra High 30747-xxx 75 - 750 Moderate 30745-xxx 55 - 490 High 30746-xxx 65 - 615 Extra High 30747-xxx 75 - 750 Moderate 30745-xxx 55 - 615 Extra High 30747-xxx 75 - 750 Moderate 30745-xxx 35 - 670 High 30747-xxx 307	surface, single lumen, filled with one	silicone gel			
Anatomical form, horizontally oval base, silicone gel filled, cohesive, dimensionally stable Profile REF Volume [ml] Low 15744-xxx 45 - 360 Moderate 15745-xxx 55 - 490 High 15746-xxx 65 - 615 Extra High 15746-xxx 45 - 360 Moderate 20744-xxx 45 - 360 Moderate 20744-xxx 45 - 360 Moderate 20744-xxx 45 - 360 Moderate 20745-xxx 45 - 360 Moderate 20745-xxx 45 - 360 Moderate 20745-xxx 55 - 490 High 20746-xxx 55 - 490 High 20746-xxx 65 - 615 Extra High 20747-xxx 75 - 750 Profile REF Volume [ml] Low 30744-xxx 45 - 360 Moderate 30745-xxx 55 - 490 High 30746-xxx 55 - 490 High 30746-xxx 55 - 490 High 30746-xxx 55 - 490 High 30747-xxx 75 - 750 Moderate 30745-xxx 55 - 490 High 30747-xxx 75 - 750 Moderate 30745-xxx 55 - 490 High 30747-xxx 75 - 750 Moderate 30745-xxx 55 - 615 Extra High 30747-xxx 75 - 750 Moderate 30745-xxx 35 - 601 Moderate 30745-xxx 35	Sublime Line				
textured surface (MESMOsensitive®) Profile REF Volume [ml]					
Low	anatomical form, horizontally oval bas	se, silicone gel fill	ed, cohesive, dime	ensionally stable	
Moderate	textured surface (MESMOsensitive®)	Profile	REF	Volume [ml]	
High	, ,	Low	15744-xxx	45 - 360	
textured surface (POLYtxt®) Profile REF Volume [ml]		Moderate	15745-xxx	55 - 490	
textured surface (POLYtxt®) Profile REF Volume [ml]		High	15746-xxx	65 - 615	
Low 20744-xxx 45 - 360 Moderate 20745-xxx 55 - 490 High 20746-xxx 65 - 615 Extra High 20747-xxx 75 - 750 To - 750 Extra High 20747-xxx 75 - 750 Micro-polyurethane foam coated Profile REF Volume [ml] Low 30744-xxx 45 - 360 Moderate 30745-xxx 55 - 490 High 30746-xxx 65 - 615 Extra High 30746-xxx 65 - 615 Extra High 30747-xxx 75 - 750 Micro-polyurethane (Microthane®) Coated surface, single lumen, filled with one silicone gel Sublime Line Optimam, anatomical form, vertically oval base, silicone gel filled, cohesive, dimensionally stable textured surface (MESMOsensitive®) Profile REF Volume [ml] Low 15774-xxx 60 - 495 Moderate 15775-xxx 75 - 670 High 15776-xxx 95 - 705 Extra High 15777-xxx 110 - 695 Profile REF Volume [ml] Low 20774-xxx 60 - 495 Moderate 20775-xxx 75 - 670 High 20776-xxx 95 - 705 Extra High 20777-xxx 110 - 695 Moderate REF Volume [ml] Low 30774-xxx 60 - 495 Moderate REF Volume [ml] Low 30774-xxx 60 - 495 Moderate REF Volume [ml] Low 30774-xxx 60 - 495 Moderate REF Volume [ml] Low 30774-xxx 60 - 495 Moderate REF Volume [ml] Low 30774-xxx 60 - 495 Moderate 30775-xxx 75 - 670 Moderate 30		Extra High	15747-xxx		
Moderate 20745-xxx 55 - 490 High 20746-xxx 65 - 615 Extra High 20746-xxx 75 - 750 The surface (Microthane®) Profile REF Volume [ml] Low 30744-xxx 45 - 360 Moderate 30745-xxx 55 - 490 High 30746-xxx 65 - 615 Extra High 30746-xxx 55 - 490 High 30746-xxx 65 - 615 Extra High 30747-xxx 75 - 750 Mammary implants of a silicone shell with textured (MESMOsensitive® or POLYtxt®) and micro-polyurethane (Microthane®) coated surface, single lumen, filled with one silicone gel Sublime Line Optimam, anatomical form, vertically oval base, silicone gel filled, cohesive, dimensionally stable textured surface (MESMOsensitive®) Profile REF Volume [ml] Low 15774-xxx 60 - 495 Moderate 15775-xxx 75 - 670 High 15777-xxx 110 - 695 Extra High 15777-xxx 110 - 695 Tother Companies Moderate 20775-xxx 75 - 670 High 20776-xxx 95 - 705 Extra High 20776-xxx 95 - 705 Extra High 20776-xxx 95 - 705 Extra High 20777-xxx 110 - 695 Extra Hi	textured surface (POLYtxt®)	Profile	REF	Volume [ml]	
High	,	Low	20744-xxx	45 - 360	
Extra High 20747-xxx 75 - 750		Moderate	20745-xxx	55 - 490	
Profile REF Volume [ml]		High	20746-xxx	65 - 615	
Low 30744-xxx 45 - 360 Moderate 30745-xxx 55 - 490 High 30746-xxx 65 - 615 Extra High 30747-xxx 75 - 750		Extra High	20747-xxx	75 - 750	
Moderate 30745-xxx 55 - 490 High 30746-xxx 65 - 615 Extra High 30746-xxx 75 - 750	micro-polyurethane foam coated	Profile	REF	Volume [ml]	
High 30746-xxx 65 - 615 Extra High 30747-xxx 75 - 750 Mammary implants of a silicone shell with textured (MESMOsensitive® or POLYtxt®) and micro-polyurethane (Microthane®) coated surface, single lumen, filled with one silicone gel Sublime Line Optimam, anatomical form, vertically oval base, silicone gel filled, cohesive, dimensionally stable textured surface (MESMOsensitive®) Profile REF Volume [ml] Low 15774-xxx 60 - 495 Moderate 15775-xxx 75 - 670 High 15776-xxx 95 - 705 Extra High 15777-xxx 110 - 695 Extra High 20774-xxx 60 - 495 Moderate 20775-xxx 75 - 670 High 20776-xxx 95 - 705 Extra High 20777-xxx 110 - 695 Extra High 207	surface (Microthane®)	Low	30744-xxx	45 - 360	
Extra High 30747-xxx 75 - 750 Mammary implants of a silicone shell with textured (MESMOsensitive® or POLYtxt®) and micro-polyurethane (Microthane®) coated surface, single lumen, filled with one silicone gel	,	Moderate	30745-xxx	55 - 490	
Mammary implants of a silicone shell with textured (MESMOsensitive® or POLYtxt®) and micro-polyurethane (Microthane®) coated surface, single lumen, filled with one silicone gel		High	30746-xxx	65 - 615	
Mammary implants of a silicone shell with textured (MESMOsensitive® or POLYtxt®) and micro-polyurethane (Microthane®) coated surface, single lumen, filled with one silicone gel		Extra High	30747-xxx	75 - 750	T
textured surface (MESMOsensitive®) Profile	surface, single lumen, filled with one s Sublime Line Optimam,	silicone gel	•	·	
Low 15774-xxx 60 - 495 Moderate 15775-xxx 75 - 670 High 15776-xxx 95 - 705 Extra High 15777-xxx 110 - 695 textured surface (POLYtxt®) Profile REF Volume [ml] Low 20774-xxx 60 - 495 Moderate 20775-xxx 75 - 670 High 20776-xxx 95 - 705 Extra High 20777-xxx 110 - 695 Extra High 20777-xxx 110 - 695 Transport Profile REF Volume [ml] Surface (Microthane®) Low 30774-xxx 60 - 495 Moderate 30775-xxx 75 - 670					
Moderate 15775-xxx 75 - 670 High 15776-xxx 95 - 705 Extra High 15777-xxx 110 - 695 textured surface (POLYtxt®) Profile REF Volume [ml] Low 20774-xxx 60 - 495 Moderate 20775-xxx 75 - 670 High 20776-xxx 95 - 705 Extra High 20777-xxx 110 - 695 micro-polyurethane foam coated Surface (Microthane®) Profile REF Volume [ml] Low 30774-xxx 60 - 495 Moderate 30775-xxx 75 - 670	textured surface (INESINOSERISITIVE)				
High 15776-xxx 95 - 705 Extra High 15777-xxx 110 - 695 textured surface (POLYtxt®) Profile REF Volume [ml] Low 20774-xxx 60 - 495 Moderate 20775-xxx 75 - 670 High 20776-xxx 95 - 705 Extra High 20777-xxx 110 - 695 micro-polyurethane foam coated Surface (Microthane®) Extra High REF Volume [ml] Low 30774-xxx 60 - 495 Moderate 30775-xxx 75 - 670					
Extra High 15777-xxx 110 - 695 textured surface (POLYtxt®) Profile REF Volume [ml] Low 20774-xxx 60 - 495 Moderate 20775-xxx 75 - 670 High 20776-xxx 95 - 705 Extra High 20777-xxx 110 - 695 micro-polyurethane foam coated Surface (Microthane®) Extra High REF Volume [ml] Low 30774-xxx 60 - 495 Moderate 30775-xxx 75 - 670					
textured surface (POLYtxt®) Profile					
Low 20774-xxx 60 - 495 Moderate 20775-xxx 75 - 670 High 20776-xxx 95 - 705 Extra High 20777-xxx 110 - 695 micro-polyurethane foam coated surface (Microthane®) Profile REF Volume [ml] Low 30774-xxx 60 - 495 Moderate 30775-xxx 75 - 670	textured surface (POLVtyt®)				
Moderate 20775-xxx 75 - 670 High 20776-xxx 95 - 705 Extra High 20777-xxx 110 - 695 micro-polyurethane foam coated surface (Microthane®) Extra High REF Volume [ml] Low 30774-xxx 60 - 495 Moderate 30775-xxx 75 - 670	textured surface (i OETIXI)				
High 20776-xxx 95 - 705 Extra High 20777-xxx 110 - 695 micro-polyurethane foam coated surface (Microthane®) Extra High 20777-xxx 110 - 695 Profile REF Volume [ml] Low 30774-xxx 60 - 495 Moderate 30775-xxx 75 - 670					
Extra High 20777-xxx 110 - 695					
micro-polyurethane foam coated surface (Microthane®) Profile REF Volume [ml] Low 30774-xxx 60 - 495 Moderate 30775-xxx 75 - 670					
surface (Microthane®) Low 30774-xxx 60 - 495 Moderate 30775-xxx 75 - 670	micro-polyurethane foam coated				
Moderate 30775-xxx 75 - 670					_
1.13.1					
Extra High 30777-xxx 110 - 695					



Product category	Product			Class	
Mammary implants of a silicone shell with					
smooth (POLYsmooth™), textured (N		or POLYtxt [®]) and			
micro-polyurethane (Microthane®) coa	ated surface, single	e lumen, filled with	one silicone gel		
Sublime Line	, 0	•	ŭ		
Coniq,					
conical form, round base, silicone gel	filled, cohesive, di	mensionally stable			
smooth surface (POLYsmooth™)	Profile	REF	Volume [ml]		
,	Low	10714-xxx	110 - 510		
	Moderate	10715-xxx	125 - 540		
	High	10716-xxx	140 - 585		
	Extra High	10717-xxx	155 - 625		
textured surface (MESMOsensitive®)	Profile	REF	Volume [ml]		
,	Low	15714-xxx	110 - 510		
	Moderate	15715-xxx	125 - 540	III	
	High 15716-xxx 140 - 585				
	Extra High	15717-xxx	155 - 625		
textured surface (POLYtxt®)	Profile	REF	Volume [ml]		
,	Low	20714-xxx	110 - 510		
	Moderate	20715-xxx	125 - 540		
	High	20716-xxx	140 - 585		
	Extra High	20717-xxx	155 - 625		
micro-polyurethane foam coated	Profile	REF	Volume [ml]		
surface (Microthane®)	Low	30714-xxx	110 - 510		
,	Moderate	30715-xxx	125 - 540		
	High	30716-xxx	140 - 585		
	Extra High	30717-xxx	155 - 625		



Product category	Product			Class
Mammary implants of a silicone sh				
textured (POLYtxt®) and micro-poly		nane®) coated surfa	ice,	
single lumen, filled with two silicone	gels			
Diagon\Gel				
Même,				
round form, round base, silicone ge			le	
textured surface (POLYtxt®)	Profile	REF	Volume [ml]	
	Low	21624-xxx	50 - 440	
	Moderate	21625-xxx	65 - 600	
	High	21626-xxx	80 - 690	
	Extra High	21627-xxx	95 - 685	
micro-polyurethane foam coated	Profile	REF	Volume [ml]	
surface (Microthane®)	Low	31624-xxx	50 - 440	
	Moderate	31625-xxx	65 - 600	
	High	31626-xxx	80 - 690	_
	Extra High	31627-xxx	95 - 685	_
Mammary implants of a silicone sh		®\		
textured (POLYtxt®) and micro-poly	urethane (Microth	nane°) coated surfa	ice,	
single lumen, filled with two silicone	gels			
Diagon\Gel				
Replicon,	aa wal fillad aaba	والمعاممة والمعالد	. atabla	
anatomical form, round base, silicon				
textured surface (POLYtxt [®])	Profile	REF	Volume [ml]	
	Low	21634-xxx	45 - 385	- III
	Moderate	21635-xxx	60 - 525	-
	High	21636-xxx	70 - 670	
asiana and a mathematical	Extra High	21637-xxx	85 - 735	
micro-polyurethane foam coated	Profile	REF	Volume [ml]	
surface (Microthane®)	Low	31634-xxx	45 - 385	
	Moderate	31635-xxx	60 - 525	
	High	31636-xxx	70 - 670	
B	Extra High	31637-xxx	85 - 735	
Mammary implants of a silicone sh				
textured (POLYtxt®) and micro-poly		nane ^s) coated surfa	ice,	
single lumen, filled with two silicone	geis			
Diagon\Gel				
Opticon , anatomical form, horizontally oval b	aca cilicana gal f	illad cabaciva dim	oncionally ctable	
	Profile	REF	Volume [ml]	
textured surface (POLYtxt®)		21644-xxx	40 - 325	_
	Low Moderate	21645-xxx	50 - 445	
				_
	High Extra High	21646-xxx	60 - 560	-
mioro polygrothono foom contad		21647-xxx	70 - 680	-
micro-polyurethane foam coated	Profile	REF	Volume [ml]	-
surface (Microthane®)	Low	31644-xxx	40 - 325	-
	Moderate	31645-xxx	50 - 445	-
	High	31646-xxx	60 - 560	_
	Extra High	31647-xxx	70 - 680	1



Product category	Product			Class
Mammary implants of a silicone sh		_		
textured (POLYtxt®) and micro-poly	urethane (Microtha	ane [®]) coated surfa	ice,	
single lumen, filled with two silicone	gels			
Diagon\Gel 4Two				
RR,				
round form, round base, cohesive, o	dimensionally stab	le		
textured surface (POLYtxt®)	Profile	REF	Volume [ml]	
,	Moderate	21621-xxx	190 - 355	
	High	21622-xxx	225 - 410	
micro-polyurethane foam coated	Profile	REF	Volume [ml]	
surface (Microthane®)	Moderate	31621-xxx	190 - 355	
,	High	31622-xxx	225 - 410	
Mammary implants of a silicone sh	ell with		•	
textured (POLYtxt®) and micro-poly		ane [®]) coated surfa	ce.	
single lumen, filled with two silicone			,	
AR,	•			
anatomical form, round base, cohes	ive, dimensionally	/ stable		
textured surface (POLYtxt®)	Profile	REF	Volume [ml]	- III
,	High	21631-xxx	195 - 480	
	Extra High	21632-xxx	240 - 500	
micro-polyurethane foam coated	Profile	REF	Volume [ml]	
surface (Microthane®)	High	31631-xxx	195 - 480	
,	Extra High	31632-xxx	240 - 500	
Mammary implants of a silicone sh		1	,	
textured (POLYtxt®) and micro-poly	urethane (Microtha	ane®) coated surfa	ice,	
single lumen, filled with two silicone		,	•	
Diagon\Gel 4Two	J			
AO,				
anatomical form, horizontally oval b				
	ase, cohesive, din	nensionally stable		
	ase, cohesive, din	nensionally stable	Volume [ml]	
textured surface (POLYtxt®)	Profile		Volume [ml] 180 - 360	
	Profile High	REF 21641-xxx	Volume [ml] 180 - 360 215 - 415	
textured surface (POLYtxt®)	Profile High Extra High	REF	180 - 360 215 - 415	
textured surface (POLYtxt®) micro-polyurethane foam coated	Profile High Extra High Profile	REF 21641-xxx 21642-xxx REF	180 - 360 215 - 415 Volume [ml]	
textured surface (POLYtxt®)	Profile High Extra High	21641-xxx 21642-xxx	180 - 360 215 - 415	

