

# EC Certificate

**mdc medical device certification GmbH**

Notified Body 0483  
herewith grants

**Polytech Health & Aesthetics GmbH**  
**Alzheimer Straße 32**  
**64807 Dieburg**  
**Germany**

for the scope

**Mammary implants of a silicone shell with  
smooth (POLYsmooth™), 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



Product category	Product			Class
<b>Mammary implants</b> of a silicone shell with smooth (POLYsmøøth™), textured (MESMOsensitive® or POLYtxt®) and micro-polyurethane (Microthane®) coated surface, single lumen, filled with one silicone gel <b>Modular System Mème,</b> round form, round base, silicone gel filled, cohesive, dimensionally stable				III
smooth surface (POLYsmøøth™)	<b>Profile</b>	<b>REF</b>	<b>Volume [ml]</b>	
	Low	10624-xxx	50 - 440	
	Moderate	10625-xxx	65 - 600	
	High	10626-xxx	80 - 690	
textured surface (MESMOsensitive®)	<b>Profile</b>	<b>REF</b>	<b>Volume [ml]</b>	
	Low	15624-xxx	50 - 440	
	Moderate	15625-xxx	65 - 600	
	High	15626-xxx	80 - 690	
textured surface (POLYtxt®)	<b>Profile</b>	<b>REF</b>	<b>Volume [ml]</b>	
	Low	20624-xxx	50 - 440	
	Moderate	20625-xxx	65 - 600	
	High	20626-xxx	80 - 690	
micro-polyurethane foam coated surface (Microthane®)	<b>Profile</b>	<b>REF</b>	<b>Volume [ml]</b>	
	Low	30624-xxx	50 - 440	
	Moderate	30625-xxx	65 - 600	
	High	30626-xxx	80 - 690	
Microthane®	<b>Profile</b>	<b>REF</b>	<b>Volume [ml]</b>	
	Low	30627-xxx	95 - 685	
	Moderate	30625-xxx	65 - 600	
	High	30626-xxx	80 - 690	
<b>Mammary implants</b> of a silicone shell with textured (MESMOsensitive® or POLYtxt®) and micro-polyurethane (Microthane®) coated surface, single lumen, filled with one silicone gel <b>Modular System Replicon,</b> anatomical form, round base, silicone gel filled, cohesive, dimensionally stable				
textured surface (MESMOsensitive®)	<b>Profile</b>	<b>REF</b>	<b>Volume [ml]</b>	
	Low	15634-xxx	45 - 385	
	Moderate	15635-xxx	60 - 525	
	High	15636-xxx	70 - 670	
textured surface (POLYtxt®)	<b>Profile</b>	<b>REF</b>	<b>Volume [ml]</b>	
	Low	20634-xxx	45 - 385	
	Moderate	20635-xxx	60 - 525	
	High	20636-xxx	70 - 670	
micro-polyurethane foam coated surface (Microthane®)	<b>Profile</b>	<b>REF</b>	<b>Volume [ml]</b>	
	Low	30634-xxx	45 - 385	
	Moderate	30635-xxx	60 - 525	
	High	30636-xxx	70 - 670	
Microthane®	<b>Profile</b>	<b>REF</b>	<b>Volume [ml]</b>	
	Low	30637-xxx	85 - 735	
	Moderate	30635-xxx	60 - 525	
	High	30636-xxx	70 - 670	
Microthane®	<b>Profile</b>	<b>REF</b>	<b>Volume [ml]</b>	
	Low	30637-xxx	85 - 735	
	Moderate	30635-xxx	60 - 525	
	High	30636-xxx	70 - 670	



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Product category	Product			Class			
<p><b>Mammary implants</b> of a silicone shell with textured (MESMOsensitive<sup>®</sup> or POLYtxt<sup>®</sup>) and micro-polyurethane (Microthane<sup>®</sup>) coated surface, single lumen, filled with one silicone gel</p> <p><b>Modular System</b> <b>Opticon</b>, anatomical form, horizontally oval base, silicone gel filled, cohesive, dimensionally stable</p>	textured surface (MESMOsensitive <sup>®</sup> )	<b>Profile</b>	<b>REF</b>	<b>Volume [ml]</b>			
		Low	15644-xxx	40 - 325			
		Moderate	15645-xxx	50 - 445			
		High	15646-xxx	60 - 560			
	textured surface (POLYtxt <sup>®</sup> )	Profile	REF	Volume [ml]			
					Low	20644-xxx	40 - 325
					Moderate	20645-xxx	50 - 445
					High	20646-xxx	60 - 560
	micro-polyurethane foam coated surface (Microthane <sup>®</sup> )	Profile	REF	Volume [ml]			
					Low	30644-xxx	40 - 325
					Moderate	30645-xxx	50 - 445
					High	30646-xxx	60 - 560
	<p><b>Mammary implants</b> of a silicone shell with textured (MESMOsensitive<sup>®</sup> or POLYtxt<sup>®</sup>) and micro-polyurethane (Microthane<sup>®</sup>) coated surface, single lumen, filled with one silicone gel</p> <p><b>Modular System</b> <b>Optimam</b>, anatomical form, vertically oval base, silicone gel filled, cohesive, dimensionally stable</p>	textured surface (MESMOsensitive <sup>®</sup> )	<b>Profile</b>	<b>REF</b>	<b>Volume [ml]</b>		
Low			15674-xxx	55 - 450			
Moderate			15675-xxx	70 - 610			
High			15676-xxx	85 - 705			
textured surface (POLYtxt <sup>®</sup> )		Profile	REF	Volume [ml]			
					Low	20674-xxx	55 - 450
					Moderate	20675-xxx	70 - 610
					High	20676-xxx	85 - 705
micro-polyurethane foam coated surface (Microthane <sup>®</sup> )		Profile	REF	Volume [ml]			
					Low	30674-xxx	55 - 450
					Moderate	30675-xxx	70 - 610
					High	30676-xxx	85 - 705
		Extra High	30677-xxx	100 - 700			

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Product category	Product			Class
<b>Mammary implants</b> of a silicone shell with smooth (POLYsmooth™), textured (MESMOsensitive® or POLYtxt®) and micro-polyurethane (Microthane®) coated surface, single lumen, filled with one silicone gel <b>Sublime Line Mème,</b> round form, round base, silicone gel filled, cohesive, dimensionally stable				III
smooth surface (POLYsmooth™)	<b>Profile</b>	<b>REF</b>	<b>Volume [ml]</b>	
	Low	10724-xxx	55 - 485	
	Moderate	10725-xxx	70 - 660	
	High	10726-xxx	90 - 690	
textured surface (MESMOsensitive®)	<b>Profile</b>	<b>REF</b>	<b>Volume [ml]</b>	
	Low	15724-xxx	55 - 485	
	Moderate	15725-xxx	70 - 660	
	High	15726-xxx	90 - 690	
textured surface (POLYtxt®)	<b>Profile</b>	<b>REF</b>	<b>Volume [ml]</b>	
	Low	20724-xxx	55 - 485	
	Moderate	20725-xxx	70 - 660	
	High	20726-xxx	90 - 690	
micro-polyurethane foam coated surface (Microthane®)	<b>Profile</b>	<b>REF</b>	<b>Volume [ml]</b>	
	Low	30724-xxx	55 - 485	
	Moderate	30725-xxx	70 - 660	
	High	30726-xxx	90 - 690	
micro-polyurethane foam coated surface (Microthane®)	<b>Profile</b>	<b>REF</b>	<b>Volume [ml]</b>	
	Low	30724-xxx	55 - 485	
	Moderate	30725-xxx	70 - 660	
	High	30726-xxx	90 - 690	
<b>Mammary implants</b> of a silicone shell with textured (MESMOsensitive® or POLYtxt®) and micro-polyurethane (Microthane®) coated surface, single lumen, filled with one silicone gel <b>Sublime Line Replicon,</b> anatomical form, round base, silicone gel filled, cohesive, dimensionally stable				
textured surface (MESMOsensitive®)	<b>Profile</b>	<b>REF</b>	<b>Volume [ml]</b>	
	Low	15734-xxx	50 - 425	
	Moderate	15735-xxx	65 - 580	
	High	15736-xxx	75 - 735	
textured surface (POLYtxt®)	<b>Profile</b>	<b>REF</b>	<b>Volume [ml]</b>	
	Low	20734-xxx	50 - 425	
	Moderate	20735-xxx	65 - 580	
	High	20736-xxx	75 - 735	
micro-polyurethane foam coated surface (Microthane®)	<b>Profile</b>	<b>REF</b>	<b>Volume [ml]</b>	
	Low	30734-xxx	50 - 425	
	Moderate	30735-xxx	65 - 580	
	High	30736-xxx	75 - 735	
micro-polyurethane foam coated surface (Microthane®)	<b>Profile</b>	<b>REF</b>	<b>Volume [ml]</b>	
	Low	30734-xxx	50 - 425	
	Moderate	30735-xxx	65 - 580	
	High	30736-xxx	75 - 735	
micro-polyurethane foam coated surface (Microthane®)	<b>Profile</b>	<b>REF</b>	<b>Volume [ml]</b>	
	Low	30734-xxx	50 - 425	
	Moderate	30735-xxx	65 - 580	
	High	30736-xxx	75 - 735	
micro-polyurethane foam coated surface (Microthane®)	<b>Profile</b>	<b>REF</b>	<b>Volume [ml]</b>	
	Low	30734-xxx	50 - 425	
	Moderate	30735-xxx	65 - 580	
	High	30736-xxx	75 - 735	



  
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Product category	Product			Class
<b>Mammary implants</b> of a silicone shell with textured (MESMOsensitive® or POLYtxt®) and micro-polyurethane (Microthane®) coated surface, single lumen, filled with one silicone gel <b>Sublime Line</b> <b>Opticon,</b> anatomical form, horizontally oval base, silicone gel filled, cohesive, dimensionally stable	textured surface (MESMOsensitive®)	<b>Profile</b>	<b>REF</b>	<b>Volume [ml]</b>
		Low	15744-xxx	45 - 360
		Moderate	15745-xxx	55 - 490
		High	15746-xxx	65 - 615
	textured surface (POLYtxt®)	<b>Profile</b>	<b>REF</b>	<b>Volume [ml]</b>
		Low	20744-xxx	45 - 360
		Moderate	20745-xxx	55 - 490
		High	20746-xxx	65 - 615
	micro-polyurethane foam coated surface (Microthane®)	<b>Profile</b>	<b>REF</b>	<b>Volume [ml]</b>
		Low	30744-xxx	45 - 360
		Moderate	30745-xxx	55 - 490
		High	30746-xxx	65 - 615
	<b>Mammary implants</b> of a silicone shell with textured (MESMOsensitive® or POLYtxt®) and micro-polyurethane (Microthane®) coated surface, single lumen, filled with one silicone gel <b>Sublime Line</b> <b>Optimam,</b> anatomical form, vertically oval base, silicone gel filled, cohesive, dimensionally stable	textured surface (MESMOsensitive®)	<b>Profile</b>	<b>REF</b>
Low			15774-xxx	60 - 495
Moderate			15775-xxx	75 - 670
High			15776-xxx	95 - 705
textured surface (POLYtxt®)		<b>Profile</b>	<b>REF</b>	<b>Volume [ml]</b>
		Low	20774-xxx	60 - 495
		Moderate	20775-xxx	75 - 670
		High	20776-xxx	95 - 705
micro-polyurethane foam coated surface (Microthane®)		<b>Profile</b>	<b>REF</b>	<b>Volume [ml]</b>
		Low	30774-xxx	60 - 495
		Moderate	30775-xxx	75 - 670
		High	30776-xxx	95 - 705
		Extra High	30777-xxx	110 - 695

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



  
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Product category	Product			Class		
<p><b>Mammary implants</b> of a silicone shell with textured (POLYtxt<sup>®</sup>) and micro-polyurethane (Microthane<sup>®</sup>) coated surface, single lumen, filled with two silicone gels  <b>Diagon\Gel Mème</b>,  round form, round base, silicone gel filled, cohesive, dimensionally stable</p>						
textured surface (POLYtxt <sup>®</sup> )	<b>Profile</b>	<b>REF</b>	<b>Volume [ml]</b>	III		
	Low	21624-xxx	50 - 440			
	Moderate	21625-xxx	65 - 600			
	High	21626-xxx	80 - 690			
micro-polyurethane foam coated surface (Microthane <sup>®</sup> )	Extra High	21627-xxx	95 - 685			
	<b>Profile</b>	<b>REF</b>	<b>Volume [ml]</b>			
	Low	31624-xxx	50 - 440			
	Moderate	31625-xxx	65 - 600			
micro-polyurethane foam coated surface (Microthane <sup>®</sup> )	High	31626-xxx	80 - 690			
	Extra High	31627-xxx	95 - 685			
	<p><b>Mammary implants</b> of a silicone shell with textured (POLYtxt<sup>®</sup>) and micro-polyurethane (Microthane<sup>®</sup>) coated surface, single lumen, filled with two silicone gels  <b>Diagon\Gel Replicon</b>,  anatomical form, round base, silicone gel filled, cohesive, dimensionally stable</p>					
	textured surface (POLYtxt <sup>®</sup> )	<b>Profile</b>	<b>REF</b>		<b>Volume [ml]</b>	
Low		21634-xxx	45 - 385			
Moderate		21635-xxx	60 - 525			
High		21636-xxx	70 - 670			
micro-polyurethane foam coated surface (Microthane <sup>®</sup> )	Extra High	21637-xxx	85 - 735			
	<b>Profile</b>	<b>REF</b>	<b>Volume [ml]</b>			
	Low	31634-xxx	45 - 385			
	Moderate	31635-xxx	60 - 525			
micro-polyurethane foam coated surface (Microthane <sup>®</sup> )	High	31636-xxx	70 - 670			
	Extra High	31637-xxx	85 - 735			
	<p><b>Mammary implants</b> of a silicone shell with textured (POLYtxt<sup>®</sup>) and micro-polyurethane (Microthane<sup>®</sup>) coated surface, single lumen, filled with two silicone gels  <b>Diagon\Gel Opticon</b>,  anatomical form, horizontally oval base, silicone gel filled, cohesive, dimensionally stable</p>					
	textured surface (POLYtxt <sup>®</sup> )	<b>Profile</b>	<b>REF</b>	<b>Volume [ml]</b>		
Low		21644-xxx	40 - 325			
Moderate		21645-xxx	50 - 445			
High		21646-xxx	60 - 560			
micro-polyurethane foam coated surface (Microthane <sup>®</sup> )	Extra High	21647-xxx	70 - 680			
	<b>Profile</b>	<b>REF</b>	<b>Volume [ml]</b>			
	Low	31644-xxx	40 - 325			
	Moderate	31645-xxx	50 - 445			
micro-polyurethane foam coated surface (Microthane <sup>®</sup> )	High	31646-xxx	60 - 560			
	Extra High	31647-xxx	70 - 680			



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Product category	Product			Class	
<b>Mammary implants</b> of a silicone shell with textured (POLYtxt <sup>®</sup> ) and micro-polyurethane (Microthane <sup>®</sup> ) coated surface, single lumen, filled with two silicone gels <b>Diagon\Gel 4Two RR,</b> round form, round base, cohesive, dimensionally stable					
textured surface (POLYtxt <sup>®</sup> )	<b>Profile</b>	<b>REF</b>	<b>Volume [ml]</b>	III	
	Moderate	21621-xxx	190 - 355		
	High	21622-xxx	225 - 410		
micro-polyurethane foam coated surface (Microthane <sup>®</sup> )	<b>Profile</b>	<b>REF</b>	<b>Volume [ml]</b>		
	Moderate	31621-xxx	190 - 355		
	High	31622-xxx	225 - 410		
<b>Mammary implants</b> of a silicone shell with textured (POLYtxt <sup>®</sup> ) and micro-polyurethane (Microthane <sup>®</sup> ) coated surface, single lumen, filled with two silicone gels <b>Diagon\Gel 4Two AR,</b> anatomical form, round base, cohesive, dimensionally stable					
textured surface (POLYtxt <sup>®</sup> )	<b>Profile</b>	<b>REF</b>	<b>Volume [ml]</b>		
	High	21631-xxx	195 - 480		
	Extra High	21632-xxx	240 - 500		
micro-polyurethane foam coated surface (Microthane <sup>®</sup> )	<b>Profile</b>	<b>REF</b>	<b>Volume [ml]</b>		
	High	31631-xxx	195 - 480		
	Extra High	31632-xxx	240 - 500		
<b>Mammary implants</b> of a silicone shell with textured (POLYtxt <sup>®</sup> ) and micro-polyurethane (Microthane <sup>®</sup> ) coated surface, single lumen, filled with two silicone gels <b>Diagon\Gel 4Two AO,</b> anatomical form, horizontally oval base, cohesive, dimensionally stable					
textured surface (POLYtxt <sup>®</sup> )	<b>Profile</b>	<b>REF</b>	<b>Volume [ml]</b>		
	High	21641-xxx	180 - 360		
	Extra High	21642-xxx	215 - 415		
micro-polyurethane foam coated surface (Microthane <sup>®</sup> )	<b>Profile</b>	<b>REF</b>	<b>Volume [ml]</b>		
	High	31641-xxx	180 - 360		
	Extra High	31642-xxx	215 - 415		



  
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