



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

No.	CE 669619
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Issued To: Euromi Biosciences

**Zoning Industriel des Plenesses 11 rue des nouvelles technologies** 

**B-4821 Andrimont** 

**Belgium** 

In respect of:

Round shaped textured and smooth silicone gel breast 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 2797):

Gary E Slack, Senior Vice President - Medical Devices

Gay C Stade

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#### **Supplementary Information to CE 669619**

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**B-4821 Andrimont** 

**Belgium** 

Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
RLMV100 RLMV125 RLMV150 RLMV175 RLMV200 RLMV220 RLMV240 RLMV260 RLMV280 RLMV300 RLMV305 RLMV350 RLMV400 RLMV450 RLMV450 RLMV500	CEREFORM® SILICONE GEL- FILLED BREAST IMPLANTS	ROUND LOW (RL), MICRO-TEXTURING (MV), CLASSICAL GEL	breast reconstruction following a mastectomy,     plastic breast augmentation / correction of various congenital or acquired abnormalities such as asymmetry, amastia, aplasia, hypomastia and hypoplasia,     replacement of an old or defective implant.	Class III
RLS100 RLS125 RLS150 RLS175 RLS200 RLS220 RLS240 RLS260 RLS280 RLS300 RLS325 RLS350 RLS400 RLS450 RLS500	CEREFORM® SILICONE GEL- FILLED BREAST IMPLANTS	ROUND LOW (RL), SMOOTH (S), CLASSICAL GEL	breast reconstruction following a mastectomy,     plastic breast augmentation / correction of various congenital or acquired abnormalities such as asymmetry, amastia, aplasia, hypomastia and hypoplasia,     replacement of an old or defective implant.	Class III

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Catalogue Number	<b>Device Name</b>	Model, Type	Intended purpose per IFU	Classification
RMMV100	CEREFORM®	ROUND MEDIUM	breast reconstruction following a	Class III
RMMV125	SILICONE GEL-	(RM),	mastectomy,	
RMMV150	FILLED BREAST	MICRO-TEXTURING	plastic breast augmentation /	
RMMV175	IMPLANTS	(MV),	correction of various congenital or	
RMMV200		CLASSICAL GEL	acquired abnormalities such as	
RMMV220			asymmetry, amastia, aplasia,	Cross )
RMMV240			hypomastia and hypoplasia,	
RMMV260			<ul> <li>replacement of an old or defective</li> </ul>	BELOW TO
RMMV280			implant.	
RMMV300				
RMMV325		3		
RMMV350				
RMMV375			CAN ASSETTABLE	
RMMV400			PAN WELL & DALK	
RMMV450		1		1 7/1
RMMV500				1000
RMMV550				
RMMV600				
RMMV650				IR VR
RMMV700				

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
RMS100	CEREFORM® SILICONE	ROUND MEDIUM	breast reconstruction following a	Class III
RMS125	GEL-FILLED BREAST	(RM),	mastectomy,	A CONTRACTOR
RMS150	IMPLANTS	SMOOTH (S),	plastic breast augmentation /	
RMS175		CLASSICAL GEL	correction of various congenital or	CONTRACT OF THE PARTY OF THE PA
RMS200			acquired abnormalities such as	(5000)
RMS220			asymmetry, amastia, aplasia,	
RMS240			hypomastia and hypoplasia,	
RMS260			replacement of an old or	
RMS280		(91	defective implant.	
RMS300		2		
RMS325				
RMS350			CAM ASSETTIBLE	
RMS375			PM VIII G DALF	
RMS400		10	107 /1007	
RMS450			W Alleman	1000
RMS500			1 (12) The second of the secon	
RMS550				
RMS600				IR IN
RMS650				
RMS700				1 131

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
RIMV150	CEREFORM® SILICONE	ROUND	breast reconstruction following a	Class III
RIMV175	GEL-FILLED BREAST	INTERMEDIATE	mastectomy,	A STATE OF
RIMV200	IMPLANTS	(RI),	<ul> <li>plastic breast augmentation /</li> </ul>	
RIMV225		MICRO-TEXTURING	correction of various congenital or	
RIMV250		(MV),	acquired abnormalities such as	(60)
RIMV275		CLASSICAL GEL	asymmetry, amastia, aplasia,	100
RIMV300			hypomastia and hypoplasia,	
RIMV325			replacement of an old or	
RIMV350		(9)	defective implant.	
RIMV375		9		
RIMV400				
RIMV450			CAM ASSETTABLE	
RIMV500			PIN THE GOALF	
RIS150	CEREFORM® SILICONE	ROUND	<ul> <li>breast reconstruction following a</li> </ul>	Class III
RIS175	GEL-FILLED BREAST	INTERMEDIATE	mastectomy,	A CONTRACTOR
RIS200	IMPLANTS	(RI), SMOOTH (S),	plastic breast augmentation /	THE
RIS225		CLASSICAL GEL	correction of various congenital or	
RIS250			acquired abnormalities such as	TR VIII
RIS275			asymmetry, amastia, aplasia,	
RIS300			hypomastia and hypoplasia,	1000
RIS325			<ul> <li>replacement of an old or</li> </ul>	
RIS350			defective implant.	
RIS375			-07111111111111111111111111111111111111	A SUL
RIS400			(A) MESSE	100
RIS450			CONTRACTOR	
RIS500				

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Catalogue Number	<b>Device Name</b>	Model, Type	Intended purpose per IFU	Classification
RHMV125	CEREFORM® SILICONE	ROUND HIGH (RH),	breast reconstruction following a	Class III
RHMV150	GEL-FILLED BREAST	MICRO-TEXTURING	mastectomy,	
RHMV175	IMPLANTS	(MV),	<ul> <li>plastic breast augmentation /</li> </ul>	
RHMV200		CLASSICAL GEL	correction of various congenital or	CONTRACT OF THE
RHMV225			acquired abnormalities such as	Or Do
RHMV250			asymmetry, amastia, aplasia,	(60)
RHMV275			hypomastia and hypoplasia,	BULLING TO
RHMV300			replacement of an old or	
RHMV325		(6)	defective implant.	
RHMV350		9		
RHMV375				
RHMV400		le le	A M ASSETTABLE TO A	
RHMV425			PINA "WEEL A DALFE	
RHMV450		100	107 /0.07 " 19	
RHMV500			M Allendary	The same of the sa
RHMV550				
RHMV600				
RHMV650				TR 40
RHMV700		1		

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
RHS125	CEREFORM® SILICONE	ROUND HIGH (RH),	breast reconstruction following a	Class III
RHS150	GEL-FILLED BREAST	SMOOTH (S),	mastectomy,	
RHS175	IMPLANTS	CLASSICAL GEL	plastic breast augmentation /	
RHS200			correction of various congenital or	
RHS225			acquired abnormalities such as	(Sr. D. )
RHS250			asymmetry, amastia, aplasia,	(69)
RHS275			hypomastia and hypoplasia,	Ble CMB C
RHS300			replacement of an old or	
RHS325			defective implant.	
RHS350		2		
RHS375				
RHS400		le le	CAM AND THE STATE OF THE STATE	
RHS425			PINA WELL A SALAR	
RHS450			1997 1997 199	
RHS500			W Alleman	A COLOR
RHS550				
RHS600				
RHS650				TA VA
RHS700		\ \	THE PROPERTY OF	

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
RVHMV130	CEREFORM® SILICONE	ROUND VERY HIGH	breast reconstruction following a	Class III
RVHMV160	GEL-FILLED BREAST	(RVH),	mastectomy,	
RVHMV190	IMPLANTS	MICRO-TEXTURING	plastic breast augmentation /	
RVHMV220		(MV),	correction of various congenital or	CONTRACT OF THE
RVHMV250		CLASSICAL GEL	acquired abnormalities such as	Or Do
RVHMV280			asymmetry, amastia, aplasia,	(60)
RVHMV310			hypomastia and hypoplasia,	BULLING TO
RVHMV340			replacement of an old or	
RVHMV370		(6)	defective implant.	
RVHMV400		9		
RVHMV450				
RVHMV500		to the	A M ASSETTABLE TO SERVE	
RVHMV550			PINA "WEEL GOALD!	
RVHMV600		100	1007 10007 " 159	
RVHMV650			W Alleman	The same of the sa
RVHMV700			7 // 19 19 19 19 19 19 19 19 19 19 19 19 19	
RVHMV750				
RVHMV800				TR 40
RVHMV900		1	THE PROPERTY	

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
RVHS130	CEREFORM® SILICONE	ROUND VERY HIGH	breast reconstruction following a	Class III
RVHS160	GEL-FILLED BREAST	(RVH),	mastectomy,	
RVHS190	IMPLANTS	SMOOTH (S),	plastic breast augmentation /	
RVHS220		CLASSICAL GEL	correction of various congenital or	
RVHS250			acquired abnormalities such as	
RVHS280			asymmetry, amastia, aplasia,	1500
RVHS310			hypomastia and hypoplasia,	7778
RVHS340			<ul> <li>replacement of an old or</li> </ul>	
RVHS370			defective implant.	
RVHS400				
RVHS450		37		
RVHS500				
RVHS550			PA II INCOMPRESSION	
RVHS600			LIVE AND COUNTY	
RVHS650			OW AND THE	
RVHS700			W Allendary	
RVHS750				1 11
RVHS800				
RVHS900				

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
RLMV100+	CEREFORM® SILICONE	ROUND LOW (RL),	breast reconstruction following a	Class III
RLMV125+	GEL-FILLED BREAST	MICRO-TEXTURING	mastectomy,	A COLL
RLMV150+	IMPLANTS	(MV),	<ul> <li>plastic breast augmentation /</li> </ul>	
RLMV175+		APTIMA GEL	correction of various congenital or	LOWEST TO SE
RLMV200+			acquired abnormalities such as	(50)
RLMV220+			asymmetry, amastia, aplasia,	160
RLMV240+			hypomastia and hypoplasia,	MICH AND
RLMV260+			replacement of an old or	
RLMV280+		(6)	defective implant.	
RLMV300+		9		
RLMV325+				
RLMV350+		le le	LA M ASSETTABLE	
RLMV400+			PAR CALL	
RLMV450+		100	707 /1007	
RLMV500+			M A Maria	1000

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
RLS100+	CEREFORM® SILICONE	ROUND LOW (RL),	breast reconstruction following a	Class III
RLS125+	GEL-FILLED BREAST	SMOOTH (S),	mastectomy,	The sales
RLS150+	IMPLANTS	APTIMA GEL	<ul> <li>plastic breast augmentation /</li> </ul>	97784
RLS175+			correction of various congenital or	1500
RLS200+			acquired abnormalities such as	
RLS220+			asymmetry, amastia, aplasia,	
RLS240+			hypomastia and hypoplasia,	
RLS260+			replacement of an old or	
RLS280+			defective implant.	
RLS300+		7		
RLS325+		0	DAY AMP APPLE	
RLS350+			My Arms	
RLS400+			17 //AS TO THE REAL (13)	ATT
RLS450+			7 17 633 133 134 17 6	
RLS500+				

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
RMMV100+	CEREFORM® SILICONE	ROUND MEDIUM	breast reconstruction following a	Class III
RMMV125+	GEL-FILLED BREAST	(RM),	mastectomy,	
RMMV150+	IMPLANTS	MICRO-TEXTURING	<ul> <li>plastic breast augmentation /</li> </ul>	
RMMV175+		(MV),	correction of various congenital or	
RMMV200+		APTIMA GEL	acquired abnormalities such as	and the
RMMV220+			asymmetry, amastia, aplasia,	(6.7)
RMMV240+			hypomastia and hypoplasia,	Section 1
RMMV260+			replacement of an old or	
RMMV280+		(9)	defective implant.	
RMMV300+		9		
RMMV325+				
RMMV350+		To the	CAM ASSETTIONS	
RMMV375+			PIN YELL GOALS	
RMMV400+			W AND " 3	
RMMV450+			W Allendary	A STATE OF THE STA
RMMV500+			7 // 10000000000000000000000000000000000	
RMMV550+				
RMMV600+				Se AU
RMMV650+				
RMMV700+				1 631

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
RMS100+	CEREFORM® SILICONE	ROUND MEDIUM	breast reconstruction following a	Class III
RMS125+	GEL-FILLED BREAST	(RM),	mastectomy,	
RMS150+	IMPLANTS	SMOOTH (S),	plastic breast augmentation /	
RMS175+		APTIMA GEL	correction of various congenital or	
RMS200+			acquired abnormalities such as	Och )
RMS220+			asymmetry, amastia, aplasia,	
RMS240+			hypomastia and hypoplasia,	BAKIN MAN
RMS260+			replacement of an old or	
RMS280+		(91	defective implant.	
RMS300+		2		
RMS325+				
RMS350+			C. II ASSETTABLE	
RMS375+			PIN WELL & SALE	
RMS400+		100	NOT AND " 19	
RMS450+			M A COMPANY	1000
RMS500+			W 1/12 mm 1	
RMS550+				
RMS600+				IR IR
RMS650+			THE PROPERTY	
RMS700+				1 138

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
RIMV150+	CEREFORM® SILICONE	ROUND	breast reconstruction following a	Class III
RIMV175+	GEL-FILLED BREAST	INTERMEDIATE	mastectomy,	
RIMV200+	IMPLANTS	(RI),	<ul> <li>plastic breast augmentation /</li> </ul>	
RIMV225+		MICRO-TEXTURING	correction of various congenital or	LOW STATE OF
RIMV250+		(MV),	acquired abnormalities such as	(50)
RIMV275+		APTIMA GEL	asymmetry, amastia, aplasia,	100
RIMV300+			hypomastia and hypoplasia,	SISTEM AND THE STATE OF THE STA
RIMV325+			replacement of an old or	
RIMV350+			defective implant.	
RIMV375+		9		
RIMV400+				
RIMV450+		le le	LAN ASSETTABLE	
RIMV500+			Call Call	

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
RIS150+	CEREFORM® SILICONE	ROUND	breast reconstruction following a	Class III
RIS175+	GEL-FILLED BREAST	INTERMEDIATE	mastectomy,	
RIS200+	IMPLANTS	(RI),	<ul> <li>plastic breast augmentation /</li> </ul>	
RIS225+		SMOOTH (S),	correction of various congenital or	
RIS250+		APTIMA GEL	acquired abnormalities such as	(Cr'0)
RIS275+			asymmetry, amastia, aplasia,	
RIS300+			hypomastia and hypoplasia,	ME COM
RIS325+			replacement of an old or	
RIS350+		(6)	defective implant.	
RIS375+		2		
RIS400+				
RIS450+			LA III AND THE STATE OF THE STA	
RIS500+			PIN WALLES	

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
RHMV125+	CEREFORM® SILICONE	ROUND HIGH (RH),	breast reconstruction following a	Class III
RHMV150+	GEL-FILLED BREAST	MICRO-TEXTURING	mastectomy,	A Comment
RHMV175+	IMPLANTS	(MV),	plastic breast augmentation /	
RHMV200+		APTIMA GEL	correction of various congenital or	
RHMV225+			acquired abnormalities such as	(Sr 03)
RHMV250+			asymmetry, amastia, aplasia,	(6.5)
RHMV275+			hypomastia and hypoplasia,	Me Com
RHMV300+			replacement of an old or	
RHMV325+			defective implant.	
RHMV350+		2		
RHMV375+				
RHMV400+		les les	CA M ASSETTABLE OF A	
RHMV425+			PAN WELL GRAIN	
RHMV450+		9	1007 ALLEY 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	
RHMV500+			M Alexander	1000
RHMV550+				
RHMV600+				
RHMV650+				DA 100
RHMV700+		\	THE PROPERTY OF	

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
RHS125+	CEREFORM® SILICONE	ROUND	breast reconstruction following a	Class III
RHS150+	GEL-FILLED BREAST	HIGH (RH)	mastectomy,	
RHS175+	IMPLANTS	SMOOTH (S)	<ul> <li>plastic breast augmentation /</li> </ul>	
RHS200+		APTIMA GEL	correction of various congenital or	CONTRACT OF THE
RHS225+			acquired abnormalities such as	(50)
RHS250+			asymmetry, amastia, aplasia,	(69)
RHS275+			hypomastia and hypoplasia,	Ble Colon
RHS300+			replacement of an old or	
RHS325+		(6)	defective implant.	
RHS350+		3		
RHS375+				
RHS400+		to the second second	A II A SECTION OF THE PARTY OF	
RHS425+			PIN WELL GOALS	
RHS450+		. 10	W AW " 19	
RHS500+			W Alleman	1000
RHS550+				
RHS600+				
RHS650+				THE PROPERTY OF
RHS700+		1		

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<b>Catalogue Number</b>	<b>Device Name</b>	Model, Type	Intended purpose per IFU	Classification
RVHMV130+	CEREFORM® SILICONE	ROUND VERY HIGH	breast reconstruction following a	Class III
RVHMV160+	GEL-FILLED BREAST	(RVH),	mastectomy,	
RVHMV190+	IMPLANTS	MICRO-TEXTURING	<ul> <li>plastic breast augmentation /</li> </ul>	
RVHMV220+		(MV),	correction of various congenital or	CONTRACT OF THE PARTY OF THE PA
RVHMV250+		APTIMA GEL	acquired abnormalities such as	(Cr'03)
RVHMV280+			asymmetry, amastia, aplasia,	1600
RVHMV310+			hypomastia and hypoplasia,	ME COM
RVHMV340+			replacement of an old or	
RVHMV370+		(6)	defective implant.	
RVHMV400+		2		
RVHMV450+				
RVHMV500+		le le	A M ASSETTABLE TO SERVE	
RVHMV550+			PINA "WEEL & SALZE	
RVHMV600+		100	1007 10007 " 1 39	
RVHMV650+			M Allendary	A CONTRACTOR
RVHMV700+			7 (17 to 18 to 18 to 19 )	
RVHMV750+				
RVHMV800+				THE ARE
RVHMV900+		1	THE PROPERTY	

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
RVHS130+	CEREFORM® SILICONE	ROUND VERY HIGH	breast reconstruction following a	Class III
RVHS160+	GEL-FILLED BREAST	(RVH),	mastectomy,	
RVHS190+	IMPLANTS	SMOOTH (S),	plastic breast augmentation /	
RVHS220+		APTIMA GEL	correction of various congenital or	CONTRACT OF THE
RVHS250+			acquired abnormalities such as	(Cro)
RVHS280+			asymmetry, amastia, aplasia,	(69)
RVHS310+			hypomastia and hypoplasia,	Blech Mich
RVHS340+			replacement of an old or	
RVHS370+			defective implant.	
RVHS400+		3		
RVHS450+				
RVHS500+		la de la decembra de	CAM AND THE STATE OF THE STATE	
RVHS550+			PINA WELL GRADE	
RVHS600+			1997 1997	
RVHS650+			W Allen	1 1000
RVHS700+				
RVHS750+				10 11/2
RVHS800+				TR VI
RVHS900+		1	THE DESIGNATION OF THE PERSON	

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
RLMV100E	CEREFORM® SILICONE	ROUND LOW (RL),	breast reconstruction following a	Class III
RLMV125E	GEL-FILLED BREAST	MICRO-TEXTURING	mastectomy,	
RLMV150E	IMPLANTS	(MV),	plastic breast augmentation /	
RLMV175E		ELLIPSE GEL	correction of various congenital or	South Street
RLMV200E			acquired abnormalities such as	(50)
RLMV220E			asymmetry, amastia, aplasia,	(60)
RLMV240E			hypomastia and hypoplasia,	
RLMV260E			replacement of an old or	
RLMV280E		(9)	defective implant.	
RLMV300E		9		
RLMV325E				
RLMV350E		le le	A M ASSETTATION	
RLMV400E			PAR TOWN OF SALES	
RLMV450E		10.	7 / / / / / / / / / / / / / / / / / / /	
RLMV500E			W Allendary	100

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
RLS100E	CEREFORM® SILICONE	ROUND LOW (RL),	breast reconstruction following a	Class III
RLS125E	GEL-FILLED BREAST	SMOOTH (S),	mastectomy,	A STATE OF THE STATE OF
RLS150E	IMPLANTS	ELLIPSE GEL	plastic breast augmentation /	
RLS175E			correction of various congenital or	Complete Manager
RLS200E			acquired abnormalities such as	Cil.
RLS220E			asymmetry, amastia, aplasia,	1000
RLS240E			hypomastia and hypoplasia,	Secretary of the second
RLS260E			replacement of an old or	
RLS280E		(91	defective implant.	
RLS300E		3		
RLS325E				
RLS350E		le le	CAM ASSETTIBLE	
RLS400E			21 VIII (2017)	
RLS450E		- 10	7 / / 9	
RLS500E				

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Catalogue Number	<b>Device Name</b>	Model, Type	Intended purpose per IFU	Classification
RMMV100E	CEREFORM® SILICONE	ROUND MEDIUM	breast reconstruction following a	Class III
RMMV125E	GEL-FILLED BREAST	(RM),	mastectomy,	
RMMV150E	IMPLANTS	MICRO-TEXTURING	<ul> <li>plastic breast augmentation /</li> </ul>	
RMMV175E		(MV),	correction of various congenital or	
RMMV200E		ELLIPSE GEL	acquired abnormalities such as	(50)
RMMV220E			asymmetry, amastia, aplasia,	
RMMV240E			hypomastia and hypoplasia,	
RMMV260E			replacement of an old or	
RMMV280E		(91	defective implant.	
RMMV300E				1 100
RMMV325E				
RMMV350E		To the second		
RMMV375E			731 Year & SA 120	
RMMV400E		10.		
RMMV450E				100
RMMV500E			7 17 12 11 11 11 11 11 11	
RMMV550E				
RMMV600E				PR VIN
RMMV650E			77 1137	
RMMV700E				1000

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
RMS100E	CEREFORM® SILICONE	ROUND MEDIUM	breast reconstruction following a	Class III
RMS125E	GEL-FILLED BREAST	(RM),	mastectomy,	A STATE OF THE STATE OF
RMS150E	IMPLANTS	SMOOTH (S),	<ul> <li>plastic breast augmentation /</li> </ul>	
RMS175E		ELLIPSE GEL	correction of various congenital or	
RMS200E			acquired abnormalities such as	(60)
RMS220E			asymmetry, amastia, aplasia,	(6.7)
RMS240E			hypomastia and hypoplasia,	HIS COMMENT
RMS260E			replacement of an old or	
RMS280E		(91	defective implant.	
RMS300E		9		
RMS325E				
RMS350E		to the second	CAN ADMITIONS	
RMS375E			PIN 12 0 0 0 1 12	
RMS400E		. 10	W AND " 3	
RMS450E			W A STATE OF	A CONTRACTOR
RMS500E			7 // 19 10 10 10 10 10 10 10 10 10 10 10 10 10	
RMS550E				
RMS600E				R VR
RMS650E		,	77 1131 -000000	
RMS700E				138

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
RIMV150E	CEREFORM® SILICONE	ROUND	breast reconstruction following a	Class III
RIMV175E	GEL-FILLED BREAST	INTERMEDIATE	mastectomy,	
RIMV200E	IMPLANTS	(RI), MICRO-	<ul> <li>plastic breast augmentation /</li> </ul>	
RIMV225E		TEXTURING (MV),	correction of various congenital or	LOWEST THE STREET
RIMV250E		ELLIPSE GEL	acquired abnormalities such as	(50)
RIMV275E			asymmetry, amastia, aplasia,	(60)
RIMV300E			hypomastia and hypoplasia,	
RIMV325E			replacement of an old or	
RIMV350E		(6)	defective implant.	
RIMV375E		2		
RIMV400E				
RIMV450E			L. 17 15-1107-1108-1108	
RIMV500E			PIN WAS GOALD	

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
RIS150E	CEREFORM® SILICONE	ROUND	breast reconstruction following a	Class III
RIS175E	GEL-FILLED BREAST	INTERMEDIATE	mastectomy,	A CONTRACTOR
RIS200E	IMPLANTS	(RI),	<ul> <li>plastic breast augmentation /</li> </ul>	
RIS225E		SMOOTH (S),	correction of various congenital or	Low Marin
RIS250E		ELLIPSE GEL	acquired abnormalities such as	Cion &
RIS275E			asymmetry, amastia, aplasia,	
RIS300E			hypomastia and hypoplasia,	MISSING AND
RIS325E			replacement of an old or	
RIS350E		(6)	defective implant.	
RIS375E		2		
RIS400E				
RIS450E			LA III AND THE STATE OF THE STA	
RIS500E			PIN THE GOLD	

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
RHMV125E	CEREFORM® SILICONE	ROUND HIGH (RH),	breast reconstruction following a	Class III
RHMV150E	GEL-FILLED BREAST	MICRO-TEXTURING	mastectomy,	
RHMV175E	IMPLANTS	(MV),	<ul> <li>plastic breast augmentation /</li> </ul>	
RHMV200E		ELLIPSE GEL	correction of various congenital or	WIND THE RESERVE
RHMV225E			acquired abnormalities such as	(Cro)
RHMV250E			asymmetry, amastia, aplasia,	(69)
RHMV275E			hypomastia and hypoplasia,	MICH MATA
RHMV300E			replacement of an old or	
RHMV325E		(6)	defective implant.	
RHMV350E		2		
RHMV375E				
RHMV400E		le le	A M ASSETTABLE TO A	
RHMV425E			PINA "WEEL A DALFE	
RHMV450E			1007 /0.007 " 159	
RHMV500E			M Alexander	1000
RHMV550E			1 (12) L	
RHMV600E				
RHMV650E				TA AS
RHMV700E		1		

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
RHS125E	CEREFORM® SILICONE	ROUND HIGH (RH),	breast reconstruction following a	Class III
RHS150E	GEL-FILLED BREAST	SMOOTH (S)	mastectomy,	
RHS175E	IMPLANTS	ELLIPSE GEL	plastic breast augmentation /	
RHS200E			correction of various congenital or	CONTRACT OF THE
RHS225E			acquired abnormalities such as	(CED)
RHS250E			asymmetry, amastia, aplasia,	(60)
RHS275E			hypomastia and hypoplasia,	BUSINESS OF THE
RHS300E			replacement of an old or	
RHS325E		(9)	defective implant.	
RHS350E		9		
RHS375E				
RHS400E		to the second second		
RHS425E			PIN WELL GRAIT	
RHS450E		10.	19	
RHS500E			W Alleman	1 100
RHS550E				
RHS600E				
RHS650E				THE PROPERTY OF
RHS700E		1	THE PROPERTY OF	

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
RVHMV130E	CEREFORM® SILICONE	ROUND VERY HIGH	breast reconstruction following a	Class III
RVHMV160E	GEL-FILLED BREAST	(RVH),	mastectomy,	
RVHMV190E	IMPLANTS	MICRO-TEXTURING	plastic breast augmentation /	
RVHMV220E		(MV),	correction of various congenital or	Control of the same
RVHMV250E		ELLIPSE GEL	acquired abnormalities such as	(St. D.)
RVHMV280E			asymmetry, amastia, aplasia,	(69)
RVHMV310E			hypomastia and hypoplasia,	MIX ONLY
RVHMV340E			replacement of an old or	
RVHMV370E			defective implant.	
RVHMV400E		9		
RVHMV450E				
RVHMV500E		le le	LAN ASSETTABLE	
RVHMV550E			THE PROPERTY OF STATES	
RVHMV600E		10.	107 / 100	
RVHMV650E			M Marine	13/0
RVHMV700E				
RVHMV750E				
RVHMV800E				The AS
RVHMV900E			THE PROPERTY	

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Catalogue Number	<b>Device Name</b>	Model, Type	Intended purpose per IFU	Classification
RVHS130E	CEREFORM® SILICONE	ROUND VERY HIGH	breast reconstruction following a	Class III
RVHS160E	GEL-FILLED BREAST	(RVH),	mastectomy,	
RVHS190E	IMPLANTS	SMOOTH (S),	plastic breast augmentation /	
RVHS220E		ELLIPSE GEL	correction of various congenital or	CONTRACT OF THE
RVHS250E			acquired abnormalities such as	Or Do
RVHS280E			asymmetry, amastia, aplasia,	(60)
RVHS310E			hypomastia and hypoplasia,	BULL OF THE
RVHS340E			replacement of an old or	
RVHS370E		(6)	defective implant.	
RVHS400E		9		
RVHS450E				
RVHS500E		to the		
RVHS550E			PIN WELL GRAIT	
RVHS600E		- 10	19	
RVHS650E			W Alleman	The same of the sa
RVHS700E				
RVHS750E				
RVHS800E				TR 40
RVHS900E		1	THE PROPERTY OF	

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
CRLMV100	CREAFORM® SILICONE	ROUND LOW (RL),	breast reconstruction following a	Class III
CRLMV125	GEL-FILLED BREAST	MICRO-TEXTURING	mastectomy,	Ser Service Co.
CRLMV150	IMPLANTS	(MV),	<ul> <li>plastic breast augmentation /</li> </ul>	
CRLMV175		CLASSICAL GEL	correction of various congenital or	South Street
CRLMV200			acquired abnormalities such as	(50)
CRLMV220			asymmetry, amastia, aplasia,	(60)
CRLMV240			hypomastia and hypoplasia,	
CRLMV260			replacement of an old or	
CRLMV280			defective implant.	
CRLMV300		9		
CRLMV325				
CRLMV350		les de la constant de	LA M ASSETTABLE TO	
CRLMV400			PAR CALL	
CRLMV450		10.	107 /100/ 19	
CRLMV500			M Alexander	A CONTRACTOR

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
CRLS100	CREAFORM® SILICONE	ROUND LOW (RL),	breast reconstruction following a	Class III
CRLS125	GEL-FILLED BREAST	SMOOTH (S),	mastectomy,	
CRLS150	IMPLANTS	CLASSICAL GEL	plastic breast augmentation /	
CRLS175			correction of various congenital or	South Market
CRLS200			acquired abnormalities such as	(50)
CRLS220			asymmetry, amastia, aplasia,	
CRLS240			hypomastia and hypoplasia,	
CRLS260			replacement of an old or	
CRLS280		(91	defective implant.	
CRLS300				
CRLS325				
CRLS350		le l	CAM ASSETTIBLE	
CRLS400			21 VIII (2017)	
CRLS450		10.	707 /1007	
CRLS500				1000

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
CRMMV100	CREAFORM® SILICONE	ROUND MEDIUM	breast reconstruction following a	Class III
CRMMV125	GEL-FILLED BREAST	(RM),	mastectomy,	
CRMMV150	IMPLANTS	MICRO-TEXTURING	<ul> <li>plastic breast augmentation /</li> </ul>	
CRMMV175		(MV),	correction of various congenital or	-049 H-11
CRMMV200		CLASSICAL GEL	acquired abnormalities such as	(CO)
CRMMV220			asymmetry, amastia, aplasia,	
CRMMV240			hypomastia and hypoplasia,	Secretary of the second
CRMMV260			replacement of an old or	
CRMMV280			defective implant.	
CRMMV300				
CRMMV325				
CRMMV350		To the second	6. 11 ASSETTIONS	
CRMMV375			P. W. A. & DALE.	
CRMMV400		10.	W AND " 3	
CRMMV450				1.00
CRMMV500				
CRMMV550				
CRMMV600				IR YR
CRMMV650		1		
CRMMV700				

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
CRMS100	CREAFORM® SILICONE	ROUND MEDIUM	breast reconstruction following a	Class III
CRMS125	GEL-FILLED BREAST	(RM),	mastectomy,	A STATE OF THE STATE OF
CRMS150	IMPLANTS	SMOOTH (S),	plastic breast augmentation /	
CRMS175		CLASSICAL GEL	correction of various congenital or	COMPANY OF THE PARK OF THE PAR
CRMS200			acquired abnormalities such as	(Cil)
CRMS220			asymmetry, amastia, aplasia,	(6)
CRMS240			hypomastia and hypoplasia,	BASIC METAL
CRMS260			replacement of an old or	
CRMS280		(91	defective implant.	
CRMS300		9		
CRMS325				
CRMS350			A 17 A SHOTT TO STATE OF	
CRMS375			PIN WELL & DAILE	
CRMS400		100	19 / 19	
CRMS450			M /A MARINA	A CONTRACTOR
CRMS500			7 // (2)	
CRMS550				
CRMS600				IR VR
CRMS650			THE PROPERTY	
CRMS700				188

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
CRIMV150	CREAFORM®	ROUND	breast reconstruction	Class III
CRIMV175	SILICONE GEL-	INTERMEDIATE	following a mastectomy,	TO THE STATE OF
CRIMV200	FILLED BREAST	(RI),	<ul> <li>plastic breast augmentation</li> </ul>	
CRIMV225	IMPLANTS	MICRO-TEXTURING	/ correction of various	
CRIMV250		(MV),	congenital or acquired	99784
CRIMV275		CLASSICAL GEL	abnormalities such as	100
CRIMV300			asymmetry, amastia, aplasia,	
CRIMV325			hypomastia and hypoplasia,	
CRIMV350		37	<ul> <li>replacement of an old or</li> </ul>	
CRIMV375		2	defective implant.	
CRIMV400		5		
CRIMV450		0.0	7 4 4 4 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	
CRIMV500			W 4000 3	

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
CRIS150	CREAFORM® SILICONE	ROUND	breast reconstruction following a	Class III
CRIS175	GEL-FILLED BREAST	INTERMEDIATE	mastectomy,	
CRIS200	IMPLANTS	(RI), SMOOTH (S),	<ul> <li>plastic breast augmentation /</li> </ul>	
CRIS225		CLASSICAL GEL	correction of various congenital or	
CRIS250			acquired abnormalities such as	(Cr. D.)
CRIS275			asymmetry, amastia, aplasia,	160
CRIS300			hypomastia and hypoplasia,	THE COURT
CRIS325			replacement of an old or	
CRIS350		(9)	defective implant.	
CRIS375		2		1000
CRIS400				
CRIS450			LA II ASSETTATION	
CRIS500			PINA WELL CLOSED	

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
CRHMV125	CREAFORM® SILICONE	ROUND HIGH (RH),	breast reconstruction following a	Class III
CRHMV150	GEL-FILLED BREAST	MICRO-TEXTURING	mastectomy,	
CRHMV175	IMPLANTS	(MV),	<ul> <li>plastic breast augmentation /</li> </ul>	
CRHMV200		CLASSICAL GEL	correction of various congenital or	CONTRACT OF THE
CRHMV225			acquired abnormalities such as	(Cr. D.)
CRHMV250			asymmetry, amastia, aplasia,	(69)
CRHMV275			hypomastia and hypoplasia,	Mich Mark
CRHMV300			replacement of an old or	
CRHMV325			defective implant.	
CRHMV350		2		
CRHMV375				
CRHMV400		le le	CAM ASSETTABLE	
CRHMV425			PM WELL A DALM	
CRHMV450			1007 /0.007 " 159	
CRHMV500			M Alexander	1000
CRHMV550			1 (12) L	
CRHMV600				10 10
CRHMV650				TA VIS
CRHMV700		\ \	ST JUNE DESIGNATION	

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
CRHS125	CREAFORM® SILICONE	ROUND HIGH (RH),	breast reconstruction following a	Class III
CRHS150	GEL-FILLED BREAST	SMOOTH (S),	mastectomy,	
CRHS175	IMPLANTS	CLASSICAL GEL	plastic breast augmentation /	
CRHS200			correction of various congenital or	CONTRACT OF THE
CRHS225			acquired abnormalities such as	Or Do
CRHS250			asymmetry, amastia, aplasia,	(60)
CRHS275			hypomastia and hypoplasia,	MILL AND TO
CRHS300			replacement of an old or	
CRHS325			defective implant.	
CRHS350		9		
CRHS375				
CRHS400		le le		
CRHS425			PINA "WEEL A SALE	
CRHS450		100	19	
CRHS500			W Alleman	The same of the sa
CRHS550			7 // 19 19 19 19 19 19 19 19 19 19 19 19 19	
CRHS600				
CRHS650				TR 40
CRHS700		\ \		

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
CRVHMV130	CREAFORM® SILICONE	ROUND VERY HIGH	breast reconstruction following a	Class III
CRVHMV160	GEL-FILLED BREAST	(RVH),	mastectomy,	A COLOR
CRVHMV190	IMPLANTS	MICRO-TEXTURING	<ul> <li>plastic breast augmentation /</li> </ul>	
CRVHMV220		(MV),	correction of various congenital or	South Market
CRVHMV250		CLASSICAL GEL	acquired abnormalities such as	(50)
CRVHMV280			asymmetry, amastia, aplasia,	160
CRVHMV310			hypomastia and hypoplasia,	MICH AND
CRVHMV340			replacement of an old or	
CRVHMV370			defective implant.	
CRVHMV400		9		
CRVHMV450				
CRVHMV500		le le	A M ASSETTABLE TO SERVE	
CRVHMV550			PINA "WEEL & SALZE	
CRVHMV600		100	1007 /0.007 " 1 59	
CRVHMV650			W Alleman	1000
CRVHMV700			7 // 19 19 19 19 19 19 19 19 19 19 19 19 19	
CRVHMV750				
CRVHMV800				DR VID
CRVHMV900			77 July 2000000	

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
CRVHS130	CREAFORM® SILICONE	ROUND VERY HIGH	breast reconstruction following a	Class III
CRVHS160	GEL-FILLED BREAST	(RVH),	mastectomy,	A COLUMN
CRVHS190	IMPLANTS	SMOOTH (S),	<ul> <li>plastic breast augmentation /</li> </ul>	
CRVHS220		CLASSICAL GEL	correction of various congenital or	
CRVHS250			acquired abnormalities such as	( P. D.)
CRVHS280			asymmetry, amastia, aplasia,	- (6)
CRVHS310			hypomastia and hypoplasia,	MICH MAN
CRVHS340			replacement of an old or	
CRVHS370		(9)	defective implant.	
CRVHS400		3		
CRVHS450				
CRVHS500			L. II ASSETTABLE	
CRVHS550			PIN WELL A DALF	
CRVHS600		10.	107 /1007	
CRVHS650			W Allenda	1000
CRVHS700				
CRVHS750				
CRVHS800				DA VID
CRVHS900		1	THE PROPERTY OF	

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Catalogue Number	<b>Device Name</b>	Model, Type	Intended purpose per IFU	Classification
CRLMV100+	CREAFORM® SILICONE	ROUND LOW (RL),	breast reconstruction following a	Class III
CRLMV125+	GEL-FILLED BREAST	MICRO-TEXTURING	mastectomy,	A COLL
CRLMV150+	IMPLANTS	(MV),	<ul> <li>plastic breast augmentation /</li> </ul>	
CRLMV175+		APTIMA GEL	correction of various congenital or	COMPANY OF THE PARK OF THE PAR
CRLMV200+			acquired abnormalities such as	(50000
CRLMV220+			asymmetry, amastia, aplasia,	(60)
CRLMV240+			hypomastia and hypoplasia,	MISSION OF THE PARTY OF THE PAR
CRLMV260+			replacement of an old or	
CRLMV280+		(9)	defective implant.	
CRLMV300+		9		
CRLMV325+				
CRLMV350+		le le	LA M ASSETTABLE	
CRLMV400+			PIN WALL GALL	
CRLMV450+		10.	707 /1007	
CRLMV500+				1000

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
CRLS100+	CREAFORM® SILICONE	ROUND LOW (RL),	breast reconstruction following a	Class III
CRLS125+	GEL-FILLED BREAST	SMOOTH (S),	mastectomy,	The state of
CRLS150+	IMPLANTS	APTIMA GEL	plastic breast augmentation /	
CRLS175+			correction of various congenital or	South Market
CRLS200+			acquired abnormalities such as	(50)
CRLS220+			asymmetry, amastia, aplasia,	- 100
CRLS240+			hypomastia and hypoplasia,	Service Control
CRLS260+			replacement of an old or	
CRLS280+		(9)	defective implant.	
CRLS300+				100
CRLS325+				
CRLS350+		No.	L. 11 ASSETTED TO STATE OF	
CRLS400+			21 VIII (2017)	
CRLS450+		10	37 / 100	
CRLS500+				100

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
CRMMV100+	CREAFORM® SILICONE	ROUND MEDIUM	breast reconstruction following a	Class III
CRMMV125+	GEL-FILLED BREAST	(RM),	mastectomy,	
CRMMV150+	IMPLANTS	MICRO-TEXTURING	plastic breast augmentation /	
CRMMV175+		(MV),	correction of various congenital or	
CRMMV200+		APTIMA GEL	acquired abnormalities such as	Cil.
CRMMV220+			asymmetry, amastia, aplasia,	(6.7)
CRMMV240+			hypomastia and hypoplasia,	BASIN TO THE
CRMMV260+			replacement of an old or	
CRMMV280+			defective implant.	
CRMMV300+		9		100
CRMMV325+				
CRMMV350+		le le	A M ASSETTIONS	
CRMMV375+			PIN THE GOLD	
CRMMV400+		10.		7/1/
CRMMV450+			W Alleman	Value 1
CRMMV500+			7 // (2) 4	
CRMMV550+				
CRMMV600+				DR YR
CRMMV650+		1		
CRMMV700+				

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
CRMS100+	CREAFORM® SILICONE	ROUND MEDIUM	breast reconstruction following a	Class III
CRMS125+	GEL-FILLED BREAST	(RM),	mastectomy,	
CRMS150+	IMPLANTS	SMOOTH (S),	plastic breast augmentation /	
CRMS175+		APTIMA GEL	correction of various congenital or	- 1991 Fill
CRMS200+			acquired abnormalities such as	(Cil)
CRMS220+			asymmetry, amastia, aplasia,	100
CRMS240+			hypomastia and hypoplasia,	BASIN OF THE
CRMS260+			replacement of an old or	
CRMS280+		(91	defective implant.	
CRMS300+		2		
CRMS325+				
CRMS350+				
CRMS375+			PIN WELL & DALLE	
CRMS400+		10	19 / 19	
CRMS450+			W Alleman	
CRMS500+				
CRMS550+				
CRMS600+				R KR
CRMS650+			THE PROPERTY	
CRMS700+				

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
CRIMV150+	CREAFORM® SILICONE	ROUND	breast reconstruction following a	Class III
CRIMV175+	GEL-FILLED BREAST	INTERMEDIATE	mastectomy,	Service Control
CRIMV200+	IMPLANTS	(RI),	plastic breast augmentation /	
CRIMV225+		MICRO-TEXTURING	correction of various congenital or	COMPANY OF THE
CRIMV250+		(MV),	acquired abnormalities such as	(Cr. D)
CRIMV275+		APTIMA GEL	asymmetry, amastia, aplasia,	160
CRIMV300+			hypomastia and hypoplasia,	BE CHAIN
CRIMV325+			replacement of an old or	
CRIMV350+			defective implant.	
CRIMV375+		2		100
CRIMV400+				
CRIMV450+		le le	A M ASSESSMENT	
CRIMV500+			PAN WELL A DALAN	

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
CRIS150+	CREAFORM® SILICONE	ROUND	breast reconstruction following a	Class III
CRIS175+	GEL-FILLED BREAST	INTERMEDIATE	mastectomy,	A CONTRACTOR
CRIS200+	IMPLANTS	(RI),	<ul> <li>plastic breast augmentation /</li> </ul>	
CRIS225+		SMOOTH (S),	correction of various congenital or	Low Marin
CRIS250+		APTIMA GEL	acquired abnormalities such as	Cion &
CRIS275+			asymmetry, amastia, aplasia,	
CRIS300+			hypomastia and hypoplasia,	MISSING AND
CRIS325+			replacement of an old or	
CRIS350+		(6)	defective implant.	
CRIS375+		3		
CRIS400+				
CRIS450+				
CRIS500+			PIN WALLES	

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
CRHMV125+ CRHMV150+ CRHMV175+ CRHMV200+ CRHMV225+ CRHMV250+ CRHMV275+ CRHMV300+ CRHMV325+ CRHMV350+ CRHMV350+ CRHMV350+ CRHMV450+ CRHMV400+ CRHMV400+	CREAFORM® SILICONE GEL-FILLED BREAST IMPLANTS	ROUND HIGH (RH), MICRO-TEXTURING (MV), APTIMA GEL	breast reconstruction following a mastectomy,     plastic breast augmentation / correction of various congenital or acquired abnormalities such as asymmetry, amastia, aplasia, hypomastia and hypoplasia,     replacement of an old or defective implant.	Class III
CRHMV550+ CRHMV550+ CRHMV600+		5	7/100000	
CRHMV650+ CRHMV700+				RA

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
CRHS125+	CREAFORM® SILICONE	ROUND	breast reconstruction following a	Class III
CRHS150+	GEL-FILLED BREAST	HIGH (RH)	mastectomy,	A COLUMN
CRHS175+	IMPLANTS	SMOOTH (S)	plastic breast augmentation /	
CRHS200+		APTIMA GEL	correction of various congenital or	
CRHS225+			acquired abnormalities such as	(Sr. D. )
CRHS250+			asymmetry, amastia, aplasia,	(69)
CRHS275+			hypomastia and hypoplasia,	Ble CMATA
CRHS300+			replacement of an old or	
CRHS325+		(6)	defective implant.	
CRHS350+		2		
CRHS375+				
CRHS400+			CA A ASSETTABLE TO A	
CRHS425+			PINA WELL CLOSELIN	
CRHS450+		- 10	197 /6/27 " 199	
CRHS500+			W Alleman	A COLOR
CRHS550+				
CRHS600+				
CRHS650+				TA VA
CRHS700+				

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
CRVHMV130+	CREAFORM® SILICONE	ROUND VERY HIGH	breast reconstruction following a	Class III
CRVHMV160+	GEL-FILLED BREAST	(RVH),	mastectomy,	
CRVHMV190+	IMPLANTS	MICRO-TEXTURING	<ul> <li>plastic breast augmentation /</li> </ul>	
CRVHMV220+		(MV),	correction of various congenital or	
CRVHMV250+		APTIMA GEL	acquired abnormalities such as	(Si D. )
CRVHMV280+			asymmetry, amastia, aplasia,	(69)
CRVHMV310+			hypomastia and hypoplasia,	BLANCE OF THE
CRVHMV340+			replacement of an old or	
CRVHMV370+			defective implant.	
CRVHMV400+		3		
CRVHMV450+				
CRVHMV500+			A M ASSETTABLE TO A	
CRVHMV550+			PM WELL A DALAN	
CRVHMV600+		10.	1997 1997	
CRVHMV650+			M Alexander	1000
CRVHMV700+				
CRVHMV750+				
CRVHMV800+				DA 100
CRVHMV900+				

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
CRVHS130+	CREAFORM® SILICONE	ROUND VERY HIGH	breast reconstruction following a	Class III
CRVHS160+	GEL-FILLED BREAST	(RVH),	mastectomy,	A COLL
CRVHS190+	IMPLANTS	SMOOTH (S),	plastic breast augmentation /	
CRVHS220+		APTIMA GEL	correction of various congenital or	COMPANY OF THE PARK OF THE PAR
CRVHS250+			acquired abnormalities such as	(50000
CRVHS280+			asymmetry, amastia, aplasia,	(6)
CRVHS310+			hypomastia and hypoplasia,	MISSION OF THE PARTY OF THE PAR
CRVHS340+			replacement of an old or	
CRVHS370+			defective implant.	
CRVHS400+		9		
CRVHS450+				
CRVHS500+		to the	CA II ASSETTATION	
CRVHS550+			PINA WELL A DALM	
CRVHS600+		100	197 /0.07 " 199	
CRVHS650+			W Alleman	1000
CRVHS700+				
CRVHS750+				
CRVHS800+				DR VID
CRVHS900+				

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
CRLMV100E	CREAFORM® SILICONE	ROUND LOW (RL),	breast reconstruction following a	Class III
CRLMV125E	GEL-FILLED BREAST	MICRO-TEXTURING	mastectomy,	The same of the same of
CRLMV150E	IMPLANTS	(MV),	<ul> <li>plastic breast augmentation /</li> </ul>	
CRLMV175E		ELLIPSE GEL	correction of various congenital or	Complete Man
CRLMV200E			acquired abnormalities such as	(CO)
CRLMV220E			asymmetry, amastia, aplasia,	(6.7)
CRLMV240E			hypomastia and hypoplasia,	BASIN TO THE
CRLMV260E			replacement of an old or	
CRLMV280E			defective implant.	
CRLMV300E		3		
CRLMV325E				
CRLMV350E		le le	A 11 ASSETTATIONS	
CRLMV400E			PART TO SALES	
CRLMV450E		10.		
CRLMV500E				13/10/

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
CRLS100E	CREAFORM® SILICONE	ROUND LOW (RL),	breast reconstruction following a	Class III
CRLS125E	GEL-FILLED BREAST	SMOOTH (S),	mastectomy,	A CONTRACTOR
CRLS150E	IMPLANTS	ELLIPSE GEL	<ul> <li>plastic breast augmentation /</li> </ul>	
CRLS175E			correction of various congenital or	COMPANY OF
CRLS200E			acquired abnormalities such as	(Sil)
CRLS220E			asymmetry, amastia, aplasia,	(64)
CRLS240E			hypomastia and hypoplasia,	BASIN TO A
CRLS260E			replacement of an old or	
CRLS280E		(91	defective implant.	
CRLS300E				
CRLS325E				
CRLS350E		To the second se	A 11 A SANT TO SANTA	
CRLS400E			PART CONTRACTOR	
CRLS450E		10	17 / 19	
CRLS500E				

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
CRMMV100E	CREAFORM® SILICONE	ROUND MEDIUM	breast reconstruction following a	Class III
CRMMV125E	GEL-FILLED BREAST	(RM),	mastectomy,	A COLOR
CRMMV150E	IMPLANTS	MICRO-TEXTURING	plastic breast augmentation /	
CRMMV175E		(MV),	correction of various congenital or	South Market
CRMMV200E		ELLIPSE GEL	acquired abnormalities such as	(50)
CRMMV220E			asymmetry, amastia, aplasia,	(6.7)
CRMMV240E			hypomastia and hypoplasia,	
CRMMV260E			replacement of an old or	
CRMMV280E			defective implant.	
CRMMV300E		9		
CRMMV325E				
CRMMV350E		To the second		
CRMMV375E			750 Years & 24 120	
CRMMV400E		. 10	W / / / / / / / / / / / / / / / / / / /	
CRMMV450E			W /4 100 has do	A AMOUNT
CRMMV500E			7 // (2)	
CRMMV550E				
CRMMV600E				A VIII
CRMMV650E				
CRMMV700E				

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
CRMS100E	CREAFORM® SILICONE	ROUND MEDIUM	breast reconstruction following a	Class III
CRMS125E	GEL-FILLED BREAST	(RM),	mastectomy,	
CRMS150E	IMPLANTS	SMOOTH (S),	<ul> <li>plastic breast augmentation /</li> </ul>	
CRMS175E		ELLIPSE GEL	correction of various congenital or	South Market
CRMS200E			acquired abnormalities such as	(50)
CRMS220E			asymmetry, amastia, aplasia,	
CRMS240E			hypomastia and hypoplasia,	
CRMS260E			replacement of an old or	
CRMS280E		(91	defective implant.	
CRMS300E		9		
CRMS325E				
CRMS350E		to the second		
CRMS375E			P. VIII & 24 12	
CRMS400E		10.	W AND " 3"	
CRMS450E			7 /2 100000 6	A TOTAL
CRMS500E			7 // 12 10 10 10 10 10 10 10 10 10 10 10 10 10	
CRMS550E				
CRMS600E				PR VIN
CRMS650E		,	77 1131	
CRMS700E				1 138

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
CRIMV150E	CREAFORM® SILICONE	ROUND	breast reconstruction following a	Class III
CRIMV175E	GEL-FILLED BREAST	INTERMEDIATE	mastectomy,	
CRIMV200E	IMPLANTS	(RI), MICRO-	<ul> <li>plastic breast augmentation /</li> </ul>	No. 2
CRIMV225E		TEXTURING (MV),	correction of various congenital or	CONTRACT OF
CRIMV250E		ELLIPSE GEL	acquired abnormalities such as	(Cr. D)
CRIMV275E			asymmetry, amastia, aplasia,	
CRIMV300E			hypomastia and hypoplasia,	BUCK WATER
CRIMV325E			replacement of an old or	
CRIMV350E		(9)	defective implant.	
CRIMV375E		2		
CRIMV400E				
CRIMV450E			A M ASSETTABLE	
CRIMV500E			PINA WALLE	

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
CRIS150E	CREAFORM® SILICONE	ROUND	breast reconstruction following a	Class III
CRIS175E	GEL-FILLED BREAST	INTERMEDIATE	mastectomy,	
CRIS200E	IMPLANTS	(RI),	<ul> <li>aesthetic breast augmentation,</li> </ul>	6.000
CRIS225E		SMOOTH (S),	plastic breast augmentation /	
CRIS250E		ELLIPSE GEL	correction of various congenital or	1000
CRIS275E			acquired abnormalities such as	91609
CRIS300E			asymmetry, amastia, aplasia,	
CRIS325E			hypomastia and hypoplasia,	
CRIS350E			replacement of an old or	
CRIS375E		37	defective implant	
CRIS400E			W W	
CRIS450E			A II III III III III III III III III II	
CRIS500E		7		

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Catalogue Number	<b>Device Name</b>	Model, Type	Intended purpose per IFU	Classification
CRHMV125E	CREAFORM® SILICONE	ROUND HIGH (RH),	breast reconstruction following a	Class III
CRHMV150E	GEL-FILLED BREAST	MICRO-TEXTURING	mastectomy,	
CRHMV175E	IMPLANTS	(MV),	<ul> <li>plastic breast augmentation /</li> </ul>	
CRHMV200E		ELLIPSE GEL	correction of various congenital or	WIND THE RESERVE
CRHMV225E			acquired abnormalities such as	(Cr. D.)
CRHMV250E			asymmetry, amastia, aplasia,	(69)
CRHMV275E			hypomastia and hypoplasia,	MICH MATA
CRHMV300E			replacement of an old or	
CRHMV325E		(6)	defective implant.	
CRHMV350E		2		
CRHMV375E				
CRHMV400E		le le	CAM ASSETTABLE	
CRHMV425E			PINA WELL A DALAN	
CRHMV450E			1007 /0.007 " 159	
CRHMV500E			M Alexander	1000
CRHMV550E			1 (12) L	
CRHMV600E				10 10
CRHMV650E				TA VIS
CRHMV700E		\ \	ST JUNE DESIGNATION	

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
CRHS125E	CREAFORM® SILICONE	ROUND HIGH (RH),	breast reconstruction following a	Class III
CRHS150E	GEL-FILLED BREAST	SMOOTH (S)	mastectomy,	
CRHS175E	IMPLANTS	ELLIPSE GEL	plastic breast augmentation /	
CRHS200E			correction of various congenital or	WIND THE REAL PROPERTY.
CRHS225E			acquired abnormalities such as	Corp.
CRHS250E			asymmetry, amastia, aplasia,	(69)
CRHS275E			hypomastia and hypoplasia,	MILL AND TO
CRHS300E			replacement of an old or	
CRHS325E		(6)	defective implant.	
CRHS350E		2		
CRHS375E				
CRHS400E			CAM ASSETTIONS	
CRHS425E			PINA WELL GOALS	
CRHS450E			19	
CRHS500E			W Alleman	1000
CRHS550E			17 (17 th 18 18 18 18 18 18 18 18 18 18 18 18 18	
CRHS600E				
CRHS650E				TA (15)
CRHS700E		\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \	THE PROPERTY OF	

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
CRVHMV130E	CREAFORM® SILICONE	ROUND VERY HIGH	breast reconstruction following a	Class III
CRVHMV160E	GEL-FILLED BREAST	(RVH),	mastectomy,	
CRVHMV190E	IMPLANTS	MICRO-TEXTURING	<ul> <li>plastic breast augmentation /</li> </ul>	
CRVHMV220E		(MV),	correction of various congenital or	STATE OF THE PARTY
CRVHMV250E		ELLIPSE GEL	acquired abnormalities such as	(Cil)
CRVHMV280E			asymmetry, amastia, aplasia,	(6)
CRVHMV310E			hypomastia and hypoplasia,	MICH MAN
CRVHMV340E			replacement of an old or	
CRVHMV370E			defective implant.	
CRVHMV400E		9		
CRVHMV450E				
CRVHMV500E		le le	A M ASSETTABLE TO SERVE	
CRVHMV550E			PINA "WEEL A DALKE	
CRVHMV600E			1007 10007 " 159	
CRVHMV650E			M Allendary	1000
CRVHMV700E				
CRVHMV750E				
CRVHMV800E				DA VID
CRVHMV900E			THE PROPERTY	

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
CRVHS130E	CREAFORM® SILICONE	ROUND VERY HIGH	breast reconstruction following a	Class III
CRVHS160E	GEL-FILLED BREAST	(RVH),	mastectomy,	
CRVHS190E	IMPLANTS	SMOOTH (S),	plastic breast augmentation /	
CRVHS220E		ELLIPSE GEL	correction of various congenital or	CONTRACT OF THE PARTY OF THE PA
CRVHS250E			acquired abnormalities such as	Or Do
CRVHS280E			asymmetry, amastia, aplasia,	(60)
CRVHS310E			hypomastia and hypoplasia,	Busin Maria
CRVHS340E			replacement of an old or	
CRVHS370E			defective implant.	
CRVHS400E		9		
CRVHS450E				
CRVHS500E		le le	( A // A / A / A / A / A / A / A / A / A	
CRVHS550E			PIN WELL GOALE	
CRVHS600E			19	
CRVHS650E			W Alleman	1 100
CRVHS700E			17 (17 th 18 18 18 18 18 18 18 18 18 18 18 18 18	
CRVHS750E				
CRVHS800E				TR VI
CRVHS900E		\ \	THE PROPERTY OF	

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
BRLMV100 BRLMV125 BRLMV150 BRLMV175 BRLMV200	EUROMI BIOSCIENCES® SILICONE GEL-FILLED BREAST IMPLANTS	ROUND LOW (RL), MICRO-TEXTURING (MV), CLASSICAL GEL	<ul> <li>breast reconstruction following a mastectomy,</li> <li>plastic breast augmentation / correction of various congenital or acquired abnormalities such as</li> </ul>	Class III
BRLMV220 BRLMV240 BRLMV260 BRLMV280 BRLMV300		9	asymmetry, amastia, aplasia, hypomastia and hypoplasia, • replacement of an old or defective implant.	
BRLMV325 BRLMV350 BRLMV400 BRLMV450			3/ 994	
BRLMV500			V Allendaria	

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
BRLS100	EUROMI BIOSCIENCES®	ROUND LOW (RL),	breast reconstruction following a	Class III
BRLS125	SILICONE GEL-FILLED	SMOOTH (S),	mastectomy,	The state of
BRLS150	BREAST IMPLANTS	CLASSICAL GEL	plastic breast augmentation /	
BRLS175			correction of various congenital or	South Market
BRLS200			acquired abnormalities such as	(50)
BRLS220			asymmetry, amastia, aplasia,	(6.0
BRLS240			hypomastia and hypoplasia,	Service Control
BRLS260			replacement of an old or	
BRLS280		(91	defective implant.	
BRLS300				100
BRLS325				
BRLS350		To the second se	L. 11 ASSETTED TO STATE OF	
BRLS400			21 VIII (2017)	
BRLS450		10	7 / / 9	
BRLS500			M A COMPANY	13/10/

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
BRMMV100	EUROMI	ROUND MEDIUM	breast reconstruction following a	Class III
BRMMV125	BIOSCIENCES®	(RM),	mastectomy,	
BRMMV150	SILICONE GEL-FILLED	MICRO-TEXTURING	plastic breast augmentation /	
BRMMV175	BREAST IMPLANTS	(MV),	correction of various congenital or	
BRMMV200		CLASSICAL GEL	acquired abnormalities such as	Oct Do
BRMMV220			asymmetry, amastia, aplasia,	
BRMMV240			hypomastia and hypoplasia,	SHE CHANGE
BRMMV260			replacement of an old or	
BRMMV280		(9)	defective implant.	
BRMMV300		9		
BRMMV325				
BRMMV350		le le	LA M ASSETTABLE	
BRMMV375			PIN YES GOALS	
BRMMV400		10.	W AND " 9	
BRMMV450				1000
BRMMV500			7 (17 th 1980) 100 (107)	
BRMMV550				
BRMMV600				R KR
BRMMV650		1	THE PROPERTY	
BRMMV700				1 100

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
BRMS100	EUROMI BIOSCIENCES®	ROUND MEDIUM	breast reconstruction following a	Class III
BRMS125	SILICONE GEL-FILLED	(RM),	mastectomy,	A CONTRACTOR
BRMS150	BREAST IMPLANTS	SMOOTH (S),	plastic breast augmentation /	
BRMS175		CLASSICAL GEL	correction of various congenital or	COMPANY OF
BRMS200			acquired abnormalities such as	(Cil)
BRMS220			asymmetry, amastia, aplasia,	(6)
BRMS240			hypomastia and hypoplasia,	BIK (MITA)
BRMS260			replacement of an old or	
BRMS280		(9)	defective implant.	
BRMS300				
BRMS325				
BRMS350			L. 11 ASSETTED TO STATE OF	
BRMS375			PIN WELL & SALE	
BRMS400			NOT AND TO S	
BRMS450			W Allenda	1000
BRMS500			7 // 100 100 100 100 100 100 100 100 100	
BRMS550				
BRMS600				IR VA
BRMS650				
BRMS700				1 131

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
BRIMV150	EUROMI	ROUND	breast reconstruction following a	Class III
BRIMV175	BIOSCIENCES®	INTERMEDIATE	mastectomy,	A COLUMN
BRIMV200	SILICONE GEL-FILLED	(RI),	plastic breast augmentation /	
BRIMV225	BREAST IMPLANTS	MICRO-TEXTURING	correction of various congenital or	CONFESSION OF THE PARTY OF THE
BRIMV250		(MV),	acquired abnormalities such as	(CC)
BRIMV275		CLASSICAL GEL	asymmetry, amastia, aplasia,	(60)
BRIMV300			hypomastia and hypoplasia,	March March
BRIMV325			replacement of an old or	
BRIMV350		(6)	defective implant.	
BRIMV375				
BRIMV400				
BRIMV450		le le	A M ASSETTION	
BRIMV500			PAN WALL COLLE	

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
BRIS150	EUROMI BIOSCIENCES®	ROUND	breast reconstruction following a	Class III
BRIS175	SILICONE GEL-FILLED	INTERMEDIATE	mastectomy,	Ser Service Co.
BRIS200	BREAST IMPLANTS	(RI), SMOOTH (S),	<ul> <li>plastic breast augmentation /</li> </ul>	
BRIS225		CLASSICAL GEL	correction of various congenital or	LOWEST THE STREET
BRIS250			acquired abnormalities such as	(50)
BRIS275			asymmetry, amastia, aplasia,	(60)
BRIS300			hypomastia and hypoplasia,	
BRIS325			replacement of an old or	
BRIS350		(6)	defective implant.	
BRIS375		2		
BRIS400				
BRIS450		to the second	LA MI ASSESSMENT OF THE PARTY O	
BRIS500			PIN WAS GOALD	

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
BRHMV125	EUROMI	ROUND HIGH (RH),	breast reconstruction following a	Class III
BRHMV150	BIOSCIENCES®	MICRO-TEXTURING	mastectomy,	
BRHMV175	SILICONE GEL-FILLED	(MV),	<ul> <li>plastic breast augmentation /</li> </ul>	ALCOHOL: NAME OF THE PARTY OF T
BRHMV200	BREAST IMPLANTS	CLASSICAL GEL	correction of various congenital or	CONTRACT OF
BRHMV225			acquired abnormalities such as	Or Do
BRHMV250			asymmetry, amastia, aplasia,	(60)
BRHMV275			hypomastia and hypoplasia,	MILL ON MAN
BRHMV300			replacement of an old or	
BRHMV325		(6)	defective implant.	
BRHMV350		2		
BRHMV375				
BRHMV400		le le	A M ASSETTABLE TO A	
BRHMV425			PINA "WEEL A DALFE	
BRHMV450		10.	197 /0.07 " 199	
BRHMV500			M Allendary	1000
BRHMV550				
BRHMV600				
BRHMV650				TA WA
BRHMV700		1		

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
BRHS125	EUROMI BIOSCIENCES®	ROUND HIGH (RH),	breast reconstruction following a	Class III
BRHS150	SILICONE GEL-FILLED	SMOOTH (S),	mastectomy,	
BRHS175	BREAST IMPLANTS	CLASSICAL GEL	<ul> <li>plastic breast augmentation /</li> </ul>	
BRHS200			correction of various congenital or	CONTRACT OF THE
BRHS225			acquired abnormalities such as	(CED)
BRHS250			asymmetry, amastia, aplasia,	(60)
BRHS275			hypomastia and hypoplasia,	Ble Colon
BRHS300			replacement of an old or	
BRHS325			defective implant.	
BRHS350		9		
BRHS375				
BRHS400		to the		
BRHS425			PIN WELL GRAIT	
BRHS450			19	
BRHS500			W Allenda	1000
BRHS550				
BRHS600				
BRHS650				THE PROPERTY OF
BRHS700		· ·	THE PROPERTY OF	

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
BRVHMV130	EUROMI	ROUND VERY HIGH	breast reconstruction following a	Class III
BRVHMV160	BIOSCIENCES®	(RVH),	mastectomy,	
BRVHMV190	SILICONE GEL-FILLED	MICRO-TEXTURING	<ul> <li>plastic breast augmentation /</li> </ul>	
BRVHMV220	BREAST IMPLANTS	(MV),	correction of various congenital or	CONTRACT OF THE
BRVHMV250		CLASSICAL GEL	acquired abnormalities such as	(Cr. D.)
BRVHMV280			asymmetry, amastia, aplasia,	(69)
BRVHMV310			hypomastia and hypoplasia,	Mich Maria
BRVHMV340			replacement of an old or	
BRVHMV370		(6)	defective implant.	
BRVHMV400		2		
BRVHMV450				
BRVHMV500			CA A ASSESSMENT	
BRVHMV550			PM WELL A DALM	
BRVHMV600		100	100 1000 1000	
BRVHMV650			M Alexander	1000
BRVHMV700				
BRVHMV750				
BRVHMV800				TA VIS
BRVHMV900		1	THE PROPERTY OF	

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
BRVHS130	EUROMI BIOSCIENCES®	ROUND VERY HIGH	breast reconstruction following a	Class III
BRVHS160	SILICONE GEL-FILLED	(RVH),	mastectomy,	
BRVHS190	BREAST IMPLANTS	SMOOTH (S),	plastic breast augmentation /	
BRVHS220		CLASSICAL GEL	correction of various congenital or	WIND THE REAL PROPERTY.
BRVHS250			acquired abnormalities such as	Corp.
BRVHS280			asymmetry, amastia, aplasia,	(69)
BRVHS310			hypomastia and hypoplasia,	MILL AND TO
BRVHS340			replacement of an old or	
BRVHS370			defective implant.	
BRVHS400		2		
BRVHS450				
BRVHS500		le le	CAM ASSETTIONS	
BRVHS550			CINA WELL GRAIN	
BRVHS600			19	
BRVHS650			W Allenda	1000
BRVHS700				
BRVHS750				
BRVHS800				TA (15)
BRVHS900		· ·	THE PROPERTY OF	

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**B-4821 Andrimont** 

**Belgium** 

Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
BRLMV100+	EUROMI	ROUND LOW (RL),	breast reconstruction following a	Class III
BRLMV125+	BIOSCIENCES®	MICRO-TEXTURING	mastectomy,	A COLL
BRLMV150+	SILICONE GEL-FILLED	(MV),	<ul> <li>plastic breast augmentation /</li> </ul>	
BRLMV175+	BREAST IMPLANTS	APTIMA GEL	correction of various congenital or	LOWEST TO L
BRLMV200+			acquired abnormalities such as	(50)
BRLMV220+			asymmetry, amastia, aplasia,	160
BRLMV240+			hypomastia and hypoplasia,	MICH AND
BRLMV260+			replacement of an old or	
BRLMV280+		(6)	defective implant.	
BRLMV300+				
BRLMV325+				
BRLMV350+		le le	A M ASSETTABLE TO A	
BRLMV400+			PAR CALL	
BRLMV450+		10.	707 1000 19	
BRLMV500+			W Allenda	A A A A A A A A A A A A A A A A A A A

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
BRLS100+	EUROMI BIOSCIENCES®	ROUND LOW (RL),	breast reconstruction following a	Class III
BRLS125+	SILICONE GEL-FILLED	SMOOTH (S),	mastectomy,	A COLUMN
BRLS150+	BREAST IMPLANTS	APTIMA GEL	<ul> <li>plastic breast augmentation /</li> </ul>	
BRLS175+			correction of various congenital or	Complete Man
BRLS200+			acquired abnormalities such as	Carl &
BRLS220+			asymmetry, amastia, aplasia,	(6.7)
BRLS240+			hypomastia and hypoplasia,	BASIN TO THE
BRLS260+			replacement of an old or	
BRLS280+			defective implant.	
BRLS300+				
BRLS325+				
BRLS350+		To the second se	L. 11 ASSETTED TO STATE OF	
BRLS400+			21 VIII (2017)	
BRLS450+			7 / / 9	
BRLS500+			W Allenda	430

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
BRMMV100+	EUROMI	ROUND MEDIUM	breast reconstruction following a	Class III
BRMMV125+	BIOSCIENCES®	(RM),	mastectomy,	A STATE OF THE STATE OF
BRMMV150+	SILICONE GEL-FILLED	MICRO-TEXTURING	plastic breast augmentation /	
BRMMV175+	BREAST IMPLANTS	(MV),	correction of various congenital or	COMPANY OF THE PARK OF THE PAR
BRMMV200+		APTIMA GEL	acquired abnormalities such as	(00)
BRMMV220+			asymmetry, amastia, aplasia,	(6)
BRMMV240+			hypomastia and hypoplasia,	
BRMMV260+			replacement of an old or	
BRMMV280+		()	defective implant.	
BRMMV300+				
BRMMV325+				
BRMMV350+		To the second		
BRMMV375+			PIN YEAR GOALD	
BRMMV400+		. 10.	W AND " 3	
BRMMV450+			W Allendary	A CONTRACTOR
BRMMV500+			7 // (2)	
BRMMV550+				
BRMMV600+				Se All
BRMMV650+		,		
BRMMV700+				

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
BRMS100+	EUROMI BIOSCIENCES®	ROUND MEDIUM	breast reconstruction following a	Class III
BRMS125+	SILICONE GEL-FILLED	(RM),	mastectomy,	A CONTRACTOR
BRMS150+	BREAST IMPLANTS	SMOOTH (S),	plastic breast augmentation /	
BRMS175+		APTIMA GEL	correction of various congenital or	South Market
BRMS200+			acquired abnormalities such as	(Cil)
BRMS220+			asymmetry, amastia, aplasia,	
BRMS240+			hypomastia and hypoplasia,	
BRMS260+			replacement of an old or	
BRMS280+		(9)	defective implant.	
BRMS300+				
BRMS325+				
BRMS350+			L. 11 ASSETTED TO STATE OF	
BRMS375+			PIN WELL & SALE	
BRMS400+			NOT AND TO S	
BRMS450+			M A COMPANY	1000
BRMS500+			W 1/12 mm 1	
BRMS550+				
BRMS600+				IR IN
BRMS650+			THE PROPERTY	
BRMS700+				1 137

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
BRIMV150+ BRIMV175+ BRIMV200+ BRIMV250+ BRIMV275+ BRIMV275+ BRIMV300+ BRIMV325+ BRIMV350+ BRIMV350+ BRIMV350+ BRIMV375+ BRIMV400+ BRIMV450+	EUROMI BIOSCIENCES® SILICONE GEL-FILLED BREAST IMPLANTS	ROUND INTERMEDIATE (RI), MICRO-TEXTURING (MV), APTIMA GEL	breast reconstruction following a mastectomy,     plastic breast augmentation / correction of various congenital or acquired abnormalities such as asymmetry, amastia, aplasia, hypomastia and hypoplasia,     replacement of an old or defective implant.	Class III
BRIMV500+			TAN WELL GRADE	

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
BRIS150+	EUROMI BIOSCIENCES®	ROUND	breast reconstruction following a	Class III
BRIS175+	SILICONE GEL-FILLED	INTERMEDIATE	mastectomy,	A CONTRACTOR
BRIS200+	BREAST IMPLANTS	(RI),	<ul> <li>plastic breast augmentation /</li> </ul>	
BRIS225+		SMOOTH (S),	correction of various congenital or	Control of the same
BRIS250+		APTIMA GEL	acquired abnormalities such as	000
BRIS275+			asymmetry, amastia, aplasia,	100
BRIS300+			hypomastia and hypoplasia,	MISSING AND
BRIS325+			replacement of an old or	
BRIS350+		(9	defective implant.	
BRIS375+		J		
BRIS400+				
BRIS450+			LA II LEADTHING	
BRIS500+			PIN WALLE	

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
BRHMV125+	EUROMI	ROUND HIGH (RH),	breast reconstruction following a	Class III
BRHMV150+	BIOSCIENCES®	MICRO-TEXTURING	mastectomy,	
BRHMV175+	SILICONE GEL-FILLED	(MV),	<ul> <li>plastic breast augmentation /</li> </ul>	
BRHMV200+	BREAST IMPLANTS	APTIMA GEL	correction of various congenital or	
BRHMV225+			acquired abnormalities such as	(Sr 03)
BRHMV250+			asymmetry, amastia, aplasia,	(69)
BRHMV275+			hypomastia and hypoplasia,	BELOW TO
BRHMV300+			replacement of an old or	
BRHMV325+			defective implant.	
BRHMV350+		2		
BRHMV375+				
BRHMV400+		la de la decimal	A M ASSETTABLE TO A	
BRHMV425+			PM WELL A DALAN	
BRHMV450+			1007 /0.007 " 1 59	
BRHMV500+			M Alexander	1000
BRHMV550+				
BRHMV600+				
BRHMV650+				DA 100
BRHMV700+		\ \		

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
BRHS125+	EUROMI BIOSCIENCES®	ROUND	breast reconstruction following a	Class III
BRHS150+	SILICONE GEL-FILLED	HIGH (RH)	mastectomy,	
BRHS175+	BREAST IMPLANTS	SMOOTH (S)	plastic breast augmentation /	
BRHS200+		APTIMA GEL	correction of various congenital or	CONTRACT OF THE
BRHS225+			acquired abnormalities such as	(Cro)
BRHS250+			asymmetry, amastia, aplasia,	(69)
BRHS275+			hypomastia and hypoplasia,	MICH MATA
BRHS300+			replacement of an old or	
BRHS325+		(6)	defective implant.	
BRHS350+		2		
BRHS375+				
BRHS400+			CAM ASSESSMENT	
BRHS425+			PINA WELL GRAIN	
BRHS450+		10.	1997 1997	
BRHS500+			W Allenda	1000
BRHS550+				
BRHS600+				10 10
BRHS650+				TA VIS
BRHS700+			THE PROPERTY	

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Catalogue Number	<b>Device Name</b>	Model, Type	Intended purpose per IFU	Classification
BRVHMV130+	EUROMI	ROUND VERY HIGH	breast reconstruction following a	Class III
BRVHMV160+	BIOSCIENCES®	(RVH),	mastectomy,	The second states
BRVHMV190+	SILICONE GEL-FILLED	MICRO-TEXTURING	plastic breast augmentation /	
BRVHMV220+	BREAST IMPLANTS	(MV),	correction of various congenital or	Low Marin
BRVHMV250+		APTÍMA GEL	acquired abnormalities such as	(500)
BRVHMV280+			asymmetry, amastia, aplasia,	1095
BRVHMV310+			hypomastia and hypoplasia,	BUSINESS OF THE PARTY OF THE PA
BRVHMV340+			replacement of an old or	
BRVHMV370+			defective implant.	
BRVHMV400+				
BRVHMV450+				
BRVHMV500+		le le	A M ASSETTION	
BRVHMV550+			THE PROPERTY OF STATES	
BRVHMV600+		10.	107 / 1007	
BRVHMV650+			W Marine	10/0
BRVHMV700+			7 // 19 19 19 19 19 19 19 19 19 19 19 19 19	
BRVHMV750+				
BRVHMV800+				TR VIS
BRVHMV900+				

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
BRVHS130+	EUROMI BIOSCIENCES®	ROUND VERY HIGH	breast reconstruction following a	Class III
BRVHS160+	SILICONE GEL-FILLED	(RVH),	mastectomy,	
BRVHS190+	BREAST IMPLANTS	SMOOTH (S),	<ul> <li>plastic breast augmentation /</li> </ul>	
BRVHS220+		APTIMA GEL	correction of various congenital or	CONTRACT OF THE
BRVHS250+			acquired abnormalities such as	Or Do
BRVHS280+			asymmetry, amastia, aplasia,	160
BRVHS310+			hypomastia and hypoplasia,	BUSINESS OF THE
BRVHS340+			replacement of an old or	
BRVHS370+			defective implant.	
BRVHS400+		9		
BRVHS450+				
BRVHS500+		to the		
BRVHS550+			PIN WELL GRAIT	
BRVHS600+		100	19	
BRVHS650+			W Alleman	1000
BRVHS700+			7 // 100 100 100 100 100 100 100 100 100	
BRVHS750+				
BRVHS800+				THE PROPERTY OF
BRVHS900+				

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
BRLMV100E	EUROMI	ROUND LOW (RL),	breast reconstruction following a	Class III
BRLMV125E	BIOSCIENCES®	MICRO-TEXTURING	mastectomy,	Ser Service Co.
BRLMV150E	SILICONE GEL-FILLED	(MV),	<ul> <li>plastic breast augmentation /</li> </ul>	
BRLMV175E	BREAST IMPLANTS	ELLIPSE GEL	correction of various congenital or	South Street
BRLMV200E			acquired abnormalities such as	(50)
BRLMV220E			asymmetry, amastia, aplasia,	- 100
BRLMV240E			hypomastia and hypoplasia,	
BRLMV260E			replacement of an old or	
BRLMV280E		(6)	defective implant.	
BRLMV300E		2		
BRLMV325E				
BRLMV350E		le le	LAN ASSETTABLE	
BRLMV400E			THE PROPERTY OF STATES	
BRLMV450E		10.	107 /100	
BRLMV500E				100

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
BRLS100E	EUROMI BIOSCIENCES®	ROUND LOW (RL),	breast reconstruction following a	Class III
BRLS125E	SILICONE GEL-FILLED	SMOOTH (S),	mastectomy,	The state of
BRLS150E	BREAST IMPLANTS	ELLIPSE GEL	<ul> <li>plastic breast augmentation /</li> </ul>	
BRLS175E			correction of various congenital or	South Market
BRLS200E			acquired abnormalities such as	(50)
BRLS220E			asymmetry, amastia, aplasia,	(6.0
BRLS240E			hypomastia and hypoplasia,	Service Control
BRLS260E			replacement of an old or	
BRLS280E		(9)	defective implant.	
BRLS300E		9		
BRLS325E				
BRLS350E		To the second se	6 11 ASSETTIBLE (SEE	
BRLS400E			PM 120 6 24 170	
BRLS450E			37 / 13	
BRLS500E				100

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
BRMMV100E	EUROMI	ROUND MEDIUM	breast reconstruction following a	Class III
BRMMV125E	BIOSCIENCES®	(RM),	mastectomy,	
BRMMV150E	SILICONE GEL-FILLED	MICRO-TEXTURING	plastic breast augmentation /	
BRMMV175E	BREAST IMPLANTS	(MV),	correction of various congenital or	September 1
BRMMV200E		ELLIPSE GEL	acquired abnormalities such as	Oct Do
BRMMV220E			asymmetry, amastia, aplasia,	
BRMMV240E			hypomastia and hypoplasia,	SHE CHANGE
BRMMV260E			replacement of an old or	
BRMMV280E		(9)	defective implant.	
BRMMV300E		9		
BRMMV325E				
BRMMV350E		le le	A M ASSETTION	
BRMMV375E			PIN THE GOALS	
BRMMV400E		10.	THE PARTY OF THE P	
BRMMV450E			W Alleman	1000
BRMMV500E				
BRMMV550E				
BRMMV600E				R KR
BRMMV650E		,		
BRMMV700E				1 100

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
BRMS100E	EUROMI BIOSCIENCES®	ROUND MEDIUM	breast reconstruction following a	Class III
BRMS125E	SILICONE GEL-FILLED	(RM),	mastectomy,	A CONTRACTOR
BRMS150E	BREAST IMPLANTS	SMOOTH (S),	<ul> <li>plastic breast augmentation /</li> </ul>	
BRMS175E		ELLIPSE GEL	correction of various congenital or	COMPANY THE
BRMS200E			acquired abnormalities such as	(50)
BRMS220E			asymmetry, amastia, aplasia,	(60)
BRMS240E			hypomastia and hypoplasia,	BASIC CONTRACTOR
BRMS260E			replacement of an old or	
BRMS280E		(91	defective implant.	
BRMS300E		9		
BRMS325E				
BRMS350E			CASE ASSETTIONS	
BRMS375E			PIN WELL & DAILE	
BRMS400E		100	19 19	
BRMS450E			W Alleman	1000
BRMS500E			7 // (2)	
BRMS550E				
BRMS600E				IR VA
BRMS650E			THE PROPERTY	
BRMS700E				100

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
BRIMV150E BRIMV175E BRIMV200E	EUROMI BIOSCIENCES® SILICONE GEL-FILLED	ROUND INTERMEDIATE (RI), MICRO-	breast reconstruction following a mastectomy,     plastic breast augmentation /	Class III
BRIMV225E BRIMV250E BRIMV275E	BREAST IMPLANTS	TEXTURING (MV), ELLIPSE GEL	correction of various congenital or acquired abnormalities such as asymmetry, amastia, aplasia,	GO CO
BRIMV300E BRIMV325E BRIMV350E		9	hypomastia and hypoplasia, • replacement of an old or defective implant.	
BRIMV375E BRIMV400E BRIMV450E				
BRIMV500E			PM 100 0 0 0 0 1 1 1 1 1 1 1 1 1 1 1 1 1	

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
BRIS150E	EUROMI BIOSCIENCES®	ROUND	breast reconstruction following a	Class III
BRIS175E	SILICONE GEL-FILLED	INTERMEDIATE	mastectomy,	
BRIS200E	BREAST IMPLANTS	(RI),	<ul> <li>plastic breast augmentation /</li> </ul>	
BRIS225E		SMOOTH (S),	correction of various congenital or	LOW BUTTON
BRIS250E		ELLIPSE GEL	acquired abnormalities such as	(Cr)
BRIS275E			asymmetry, amastia, aplasia,	160
BRIS300E			hypomastia and hypoplasia,	
BRIS325E			replacement of an old or	
BRIS350E		(6)	defective implant.	
BRIS375E		20		100 M
BRIS400E				
BRIS450E		to the second	A M RESERVED	
BRIS500E			PIN WELL GOLD	

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
BRHMV125E	EUROMI	ROUND HIGH (RH),	breast reconstruction following a	Class III
BRHMV150E	BIOSCIENCES®	MICRO-TEXTURING	mastectomy,	
BRHMV175E	SILICONE GEL-FILLED	(MV),	<ul> <li>plastic breast augmentation /</li> </ul>	
BRHMV200E	BREAST IMPLANTS	ELLIPSE GEL	correction of various congenital or	WIND THE REAL PROPERTY.
BRHMV225E			acquired abnormalities such as	Corp.
BRHMV250E			asymmetry, amastia, aplasia,	(69)
BRHMV275E			hypomastia and hypoplasia,	MILL AND TO
BRHMV300E			replacement of an old or	
BRHMV325E		(6)	defective implant.	
BRHMV350E		2		
BRHMV375E				
BRHMV400E		le le	A M ASSETTABLE	
BRHMV425E			PINA WELL A DALM	
BRHMV450E		10.	W AND " 19	
BRHMV500E			W Allenda	The same of the sa
BRHMV550E				
BRHMV600E				
BRHMV650E				The VIS
BRHMV700E		,	THE PROPERTY AND ADDRESS OF	

First Issued: **2021-04-02** Date: **2021-04-02** Expiry Date: **2024-05-26** 

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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.





### **Supplementary Information to CE 669619**

Issued To: Euromi Biosciences

**Zoning Industriel des Plenesses** 11 rue des nouvelles technologies

**B-4821 Andrimont** 

**Belgium** 

Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
BRHS125E	EUROMI BIOSCIENCES®	ROUND HIGH (RH),	breast reconstruction following a	Class III
BRHS150E	SILICONE GEL-FILLED	SMOOTH (S)	mastectomy,	A COLUMN
BRHS175E	BREAST IMPLANTS	ELLIPSE GEL	plastic breast augmentation /	The same of the sa
BRHS200E			correction of various congenital or	LOWES TO THE
BRHS225E			acquired abnormalities such as	(500)
BRHS250E			asymmetry, amastia, aplasia,	- (60)
BRHS275E			hypomastia and hypoplasia,	Mile War
BRHS300E			replacement of an old or	
BRHS325E			defective implant.	
BRHS350E		9		
BRHS375E				
BRHS400E		to the		
BRHS425E			PINA "WEEL A SALE	
BRHS450E		10.	7 / / 9	
BRHS500E				100
BRHS550E			7 // 100 100 100 100 100 100 100 100 100	
BRHS600E				
BRHS650E				DR VID
BRHS700E				

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
BRVHMV130E	EUROMI	ROUND VERY HIGH	breast reconstruction following a	Class III
BRVHMV160E	BIOSCIENCES®	(RVH),	mastectomy,	
BRVHMV190E	SILICONE GEL-FILLED	MICRO-TEXTURING	<ul> <li>plastic breast augmentation /</li> </ul>	A PART OF THE PART
BRVHMV220E	BREAST IMPLANTS	(MV),	correction of various congenital or	CONTRACT OF
BRVHMV250E		ELLIPSE GEL	acquired abnormalities such as	(500)
BRVHMV280E			asymmetry, amastia, aplasia,	(60)
BRVHMV310E			hypomastia and hypoplasia,	MILL ON MAN
BRVHMV340E			replacement of an old or	
BRVHMV370E		(6)	defective implant.	
BRVHMV400E				
BRVHMV450E				
BRVHMV500E		le le	A M ASSETTABLE TO A	
BRVHMV550E			PINA "WEEL A DALFE	
BRVHMV600E		10.	107 /0.07 " 19	
BRVHMV650E			M Allendary	1000
BRVHMV700E			1 (19 mm) 1 mm (1) 2	
BRVHMV750E				
BRVHMV800E				TA WA
BRVHMV900E		1		

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**Belgium** 

Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
BRVHS130E	EUROMI BIOSCIENCES®	ROUND VERY HIGH	breast reconstruction following a	Class III
BRVHS160E	SILICONE GEL-FILLED	(RVH),	mastectomy,	and the second
BRVHS190E	BREAST IMPLANTS	SMOOTH (S),	plastic breast augmentation /	
BRVHS220E		ELLIPSE GEL	correction of various congenital or	CONTRACT OF THE
BRVHS250E			acquired abnormalities such as	(500)
BRVHS280E			asymmetry, amastia, aplasia,	(60)
BRVHS310E			hypomastia and hypoplasia,	Ble Colon
BRVHS340E			replacement of an old or	
BRVHS370E			defective implant.	
BRVHS400E		9		
BRVHS450E				
BRVHS500E		le le		
BRVHS550E			PIN WELL GRAIT	
BRVHS600E				
BRVHS650E			W Allenda	1 100
BRVHS700E			7 (7 Emm 1981) (3)	
BRVHS750E				
BRVHS800E				THE PROPERTY OF
BRVHS900E		1	THE PROPERTY	

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**Supplementary Information to CE 669619** 

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**Zoning Industriel des Plenesses** 11 rue des nouvelles technologies

**B-4821 Andrimont** 

**Belgium** 

# **Certificate History**

Date	Reference Number		Action
Current	8694762	Issued.	

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**Supplementary Information to CE 669619 -** Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3

Issued to: **Euromi Biosciences** 

**Zoning Industriel des Plenesses 11 rue des nouvelles technologies** 

**B-4821 Andrimont** 

**Belgium** 

**Date:** 25 April 2023

### **Changes Approved:**

Date	Reference Number	Action
03 August 2022	3446738	Addition of manufacturing location Euromi
		Biosciences France for manufacture of
		CEREFORM®, CREAFORM®, and EUROMI
		BIOSCIENCES round silicone gel-filled breast
		implants
25 April 2023	3792061	Amended – Change in cross-linking and sterilisation
		oven.
		Amended – Shelf-life extension to 5 years.



### Inspiring trust for a more resilient world.

25 April 2023

Euromi Biosciences Zoning Industriel des Plenesses 11 rue des nouvelles technologies B-4821 Andrimont Belgium

To whom it may concern,

The transitional provisions specified in MDR Article 120(3) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26<sup>th</sup> May 2021.

This letter is to confirm that BSI has reviewed and approved the change(s) detailed in the table below. These changes do not represent a significant change in design or intended purpose under MDR Article 120(3) and as per the guidance provided in MDCG 2020-3. The related MDD certificate specified below remains valid until the expiry date specified on the certificate.

Certificate	Directive and Annex	Reference Number	Changes approved
CE 669619	93/42/EEC Annex II Section 4	3792061	Amended – Change in cross-linking and sterilisation oven. Amended – Shelf-life extension to 5 years.

Should you have any queries concerning your certification, or if we can be of further assistance to you, please contact your BSI Scheme Manager.

Yours sincerely,

Graeme Tunbridge

Say Building

John M. Keynesplein 9 1066 EP Amsterdam The Netherlands

Senior Vice President, Medical Devices

