

EC Design-Examination Certificate

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

No.**CE 669619****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

First Issued: **2021-04-02**

Date: **2021-04-02**

Expiry Date: **2024-05-26**

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EC Design-Examination Certificate

Supplementary Information to CE 669619

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
RLMV100 RLMV125 RLMV150 RLMV175 RLMV200 RLMV220 RLMV240 RLMV260 RLMV280 RLMV300 RLMV325 RLMV350 RLMV400 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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RIS150 RIS175 RIS200 RIS225 RIS250 RIS275 RIS300 RIS325 RIS350 RIS375 RIS400 RIS450 RIS500	CEREFORM® SILICONE GEL-FILLED BREAST IMPLANTS	ROUND INTERMEDIATE (RI), 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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Issued To:

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

Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
RLMV100E RLMV125E RLMV150E RLMV175E RLMV200E RLMV220E RLMV240E RLMV260E RLMV280E RLMV300E RLMV325E RLMV350E RLMV400E RLMV450E RLMV500E	CEREFORM® SILICONE GEL-FILLED BREAST IMPLANTS	ROUND LOW (RL), MICRO-TEXTURING (MV), ELLIPSE 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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Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
RLS100E RLS125E RLS150E RLS175E RLS200E RLS220E RLS240E RLS260E RLS280E RLS300E RLS325E RLS350E RLS400E RLS450E RLS500E	CEREFORM® SILICONE GEL-FILLED BREAST IMPLANTS	ROUND LOW (RL), SMOOTH (S), ELLIPSE 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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RMMV100E RMMV125E RMMV150E RMMV175E RMMV200E RMMV220E RMMV240E RMMV260E RMMV280E RMMV300E RMMV325E RMMV350E RMMV375E RMMV400E RMMV450E RMMV500E RMMV550E RMMV600E RMMV650E RMMV700E	CEREFORM® SILICONE GEL-FILLED BREAST IMPLANTS	ROUND MEDIUM (RM), MICRO-TEXTURING (MV), ELLIPSE 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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RMS100E RMS125E RMS150E RMS175E RMS200E RMS220E RMS240E RMS260E RMS280E RMS300E RMS325E RMS350E RMS375E RMS400E RMS450E RMS500E RMS550E RMS600E RMS650E RMS700E	CEREFORM® SILICONE GEL-FILLED BREAST IMPLANTS	ROUND MEDIUM (RM), SMOOTH (S), ELLIPSE 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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RIMV150E RIMV175E RIMV200E RIMV225E RIMV250E RIMV275E RIMV300E RIMV325E RIMV350E RIMV375E RIMV400E RIMV450E RIMV500E	CEREFORM® SILICONE GEL-FILLED BREAST IMPLANTS	ROUND INTERMEDIATE (RI), MICRO- TEXTURING (MV), ELLIPSE 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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RIS150E RIS175E RIS200E RIS225E RIS250E RIS275E RIS300E RIS325E RIS350E RIS375E RIS400E RIS450E RIS500E	CEREFORM® SILICONE GEL-FILLED BREAST IMPLANTS	ROUND INTERMEDIATE (RI), SMOOTH (S), ELLIPSE 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	Device Name	Model, Type	Intended purpose per IFU	Classification
RHMOV125E RHMOV150E RHMOV175E RHMOV200E RHMOV225E RHMOV250E RHMOV275E RHMOV300E RHMOV325E RHMOV350E RHMOV375E RHMOV400E RHMOV425E RHMOV450E RHMOV500E RHMOV550E RHMOV600E RHMOV650E RHMOV700E	CEREFORM® SILICONE GEL-FILLED BREAST IMPLANTS	ROUND HIGH (RH), MICRO-TEXTURING (MV), ELLIPSE 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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RHS125E RHS150E RHS175E RHS200E RHS225E RHS250E RHS275E RHS300E RHS325E RHS350E RHS375E RHS400E RHS425E RHS450E RHS500E RHS550E RHS600E RHS650E RHS700E	CEREFORM® SILICONE GEL-FILLED BREAST IMPLANTS	ROUND HIGH (RH), SMOOTH (S) ELLIPSE 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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RVHMOV130E RVHMOV160E RVHMOV190E RVHMOV220E RVHMOV250E RVHMOV280E RVHMOV310E RVHMOV340E RVHMOV370E RVHMOV400E RVHMOV450E RVHMOV500E RVHMOV550E RVHMOV600E RVHMOV650E RVHMOV700E RVHMOV750E RVHMOV800E RVHMOV900E	CEREFORM® SILICONE GEL-FILLED BREAST IMPLANTS	ROUND VERY HIGH (RVH), MICRO-TEXTURING (MV), ELLIPSE 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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RVHS130E RVHS160E RVHS190E RVHS220E RVHS250E RVHS280E RVHS310E RVHS340E RVHS370E RVHS400E RVHS450E RVHS500E RVHS550E RVHS600E RVHS650E RVHS700E RVHS750E RVHS800E RVHS900E	CEREFORM® SILICONE GEL-FILLED BREAST IMPLANTS	ROUND VERY HIGH (RVH), SMOOTH (S), ELLIPSE 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	Device Name	Model, Type	Intended purpose per IFU	Classification
CRLMV100 CRLMV125 CRLMV150 CRLMV175 CRLMV200 CRLMV220 CRLMV240 CRLMV260 CRLMV280 CRLMV300 CRLMV325 CRLMV350 CRLMV400 CRLMV450 CRLMV500	CREAFORM® 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

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
CRLS100 CRLS125 CRLS150 CRLS175 CRLS200 CRLS220 CRLS240 CRLS260 CRLS280 CRLS300 CRLS325 CRLS350 CRLS400 CRLS450 CRLS500	CREAFORM® 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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CRMMV100 CRMMV125 CRMMV150 CRMMV175 CRMMV200 CRMMV220 CRMMV240 CRMMV260 CRMMV280 CRMMV300 CRMMV325 CRMMV350 CRMMV375 CRMMV400 CRMMV450 CRMMV500 CRMMV550 CRMMV600 CRMMV650 CRMMV700	CREAFORM® SILICONE GEL-FILLED BREAST IMPLANTS	ROUND MEDIUM (RM), 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

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CRMS100 CRMS125 CRMS150 CRMS175 CRMS200 CRMS220 CRMS240 CRMS260 CRMS280 CRMS300 CRMS325 CRMS350 CRMS375 CRMS400 CRMS450 CRMS500 CRMS550 CRMS600 CRMS650 CRMS700	CREAFORM® SILICONE GEL-FILLED BREAST IMPLANTS	ROUND MEDIUM (RM), 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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CRIMV150 CRIMV175 CRIMV200 CRIMV225 CRIMV250 CRIMV275 CRIMV300 CRIMV325 CRIMV350 CRIMV375 CRIMV400 CRIMV450 CRIMV500	CREAFORM® SILICONE GEL- FILLED BREAST IMPLANTS	ROUND INTERMEDIATE (RI), 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

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CRIS150 CRIS175 CRIS200 CRIS225 CRIS250 CRIS275 CRIS300 CRIS325 CRIS350 CRIS375 CRIS400 CRIS450 CRIS500	CREAFORM® SILICONE GEL-FILLED BREAST IMPLANTS	ROUND INTERMEDIATE (RI), 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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CRHVM125 CRHVM150 CRHVM175 CRHVM200 CRHVM225 CRHVM250 CRHVM275 CRHVM300 CRHVM325 CRHVM350 CRHVM375 CRHVM400 CRHVM425 CRHVM450 CRHVM500 CRHVM550 CRHVM600 CRHVM650 CRHVM700	CREAFORM® SILICONE GEL-FILLED BREAST IMPLANTS	ROUND HIGH (RH), 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

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CRHS125 CRHS150 CRHS175 CRHS200 CRHS225 CRHS250 CRHS275 CRHS300 CRHS325 CRHS350 CRHS375 CRHS400 CRHS425 CRHS450 CRHS500 CRHS550 CRHS600 CRHS650 CRHS700	CREAFORM® SILICONE GEL-FILLED BREAST IMPLANTS	ROUND HIGH (RH), 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	Device Name	Model, Type	Intended purpose per IFU	Classification
CRVHVMV130 CRVHVMV160 CRVHVMV190 CRVHVMV220 CRVHVMV250 CRVHVMV280 CRVHVMV310 CRVHVMV340 CRVHVMV370 CRVHVMV400 CRVHVMV450 CRVHVMV500 CRVHVMV550 CRVHVMV600 CRVHVMV650 CRVHVMV700 CRVHVMV750 CRVHVMV800 CRVHVMV900	CREAFORM® SILICONE GEL-FILLED BREAST IMPLANTS	ROUND VERY HIGH (RVH), 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

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CRVHS130 CRVHS160 CRVHS190 CRVHS220 CRVHS250 CRVHS280 CRVHS310 CRVHS340 CRVHS370 CRVHS400 CRVHS450 CRVHS500 CRVHS550 CRVHS600 CRVHS650 CRVHS700 CRVHS750 CRVHS800 CRVHS900	CREAFORM® SILICONE GEL-FILLED BREAST IMPLANTS	ROUND VERY HIGH (RVH), 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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Supplementary Information to CE 669619

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

Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
CRLMV100+ CRLMV125+ CRLMV150+ CRLMV175+ CRLMV200+ CRLMV220+ CRLMV240+ CRLMV260+ CRLMV280+ CRLMV300+ CRLMV325+ CRLMV350+ CRLMV400+ CRLMV450+ CRLMV500+	CREAFORM® SILICONE GEL-FILLED BREAST IMPLANTS	ROUND LOW (RL), 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

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
CRLS100+ CRLS125+ CRLS150+ CRLS175+ CRLS200+ CRLS220+ CRLS240+ CRLS260+ CRLS280+ CRLS300+ CRLS325+ CRLS350+ CRLS400+ CRLS450+ CRLS500+	CREAFORM® SILICONE GEL-FILLED BREAST IMPLANTS	ROUND LOW (RL), SMOOTH (S), 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

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CRMMV100+ CRMMV125+ CRMMV150+ CRMMV175+ CRMMV200+ CRMMV220+ CRMMV240+ CRMMV260+ CRMMV280+ CRMMV300+ CRMMV325+ CRMMV350+ CRMMV375+ CRMMV400+ CRMMV450+ CRMMV500+ CRMMV550+ CRMMV600+ CRMMV650+ CRMMV700+	CREAFORM® SILICONE GEL-FILLED BREAST IMPLANTS	ROUND MEDIUM (RM), 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

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CRMS100+ CRMS125+ CRMS150+ CRMS175+ CRMS200+ CRMS220+ CRMS240+ CRMS260+ CRMS280+ CRMS300+ CRMS325+ CRMS350+ CRMS375+ CRMS400+ CRMS450+ CRMS500+ CRMS550+ CRMS600+ CRMS650+ CRMS700+	CREAFORM® SILICONE GEL-FILLED BREAST IMPLANTS	ROUND MEDIUM (RM), SMOOTH (S), 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

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
CRIMV150+ CRIMV175+ CRIMV200+ CRIMV225+ CRIMV250+ CRIMV275+ CRIMV300+ CRIMV325+ CRIMV350+ CRIMV375+ CRIMV400+ CRIMV450+ CRIMV500+	CREAFORM® 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

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CRIS150+ CRIS175+ CRIS200+ CRIS225+ CRIS250+ CRIS275+ CRIS300+ CRIS325+ CRIS350+ CRIS375+ CRIS400+ CRIS450+ CRIS500+	CREAFORM® SILICONE GEL-FILLED BREAST IMPLANTS	ROUND INTERMEDIATE (RI), SMOOTH (S), 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

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
CRHMOV125+ CRHMOV150+ CRHMOV175+ CRHMOV200+ CRHMOV225+ CRHMOV250+ CRHMOV275+ CRHMOV300+ CRHMOV325+ CRHMOV350+ CRHMOV375+ CRHMOV400+ CRHMOV425+ CRHMOV450+ CRHMOV500+ CRHMOV550+ CRHMOV600+ CRHMOV650+ CRHMOV700+	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

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
CRHS125+ CRHS150+ CRHS175+ CRHS200+ CRHS225+ CRHS250+ CRHS275+ CRHS300+ CRHS325+ CRHS350+ CRHS375+ CRHS400+ CRHS425+ CRHS450+ CRHS500+ CRHS550+ CRHS600+ CRHS650+ CRHS700+	CREAFORM® SILICONE GEL-FILLED BREAST IMPLANTS	ROUND HIGH (RH) SMOOTH (S) 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

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CRVHVMV130+ CRVHVMV160+ CRVHVMV190+ CRVHVMV220+ CRVHVMV250+ CRVHVMV280+ CRVHVMV310+ CRVHVMV340+ CRVHVMV370+ CRVHVMV400+ CRVHVMV450+ CRVHVMV500+ CRVHVMV550+ CRVHVMV600+ CRVHVMV650+ CRVHVMV700+ CRVHVMV750+ CRVHVMV800+ CRVHVMV900+	CREAFORM® SILICONE GEL-FILLED BREAST IMPLANTS	ROUND VERY HIGH (RVH), 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

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
CRVHS130+ CRVHS160+ CRVHS190+ CRVHS220+ CRVHS250+ CRVHS280+ CRVHS310+ CRVHS340+ CRVHS370+ CRVHS400+ CRVHS450+ CRVHS500+ CRVHS550+ CRVHS600+ CRVHS650+ CRVHS700+ CRVHS750+ CRVHS800+ CRVHS900+	CREAFORM® SILICONE GEL-FILLED BREAST IMPLANTS	ROUND VERY HIGH (RVH), SMOOTH (S), 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

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
CRLMV100E CRLMV125E CRLMV150E CRLMV175E CRLMV200E CRLMV220E CRLMV240E CRLMV260E CRLMV280E CRLMV300E CRLMV325E CRLMV350E CRLMV400E CRLMV450E CRLMV500E	CREAFORM® SILICONE GEL-FILLED BREAST IMPLANTS	ROUND LOW (RL), MICRO-TEXTURING (MV), ELLIPSE 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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CRLS100E CRLS125E CRLS150E CRLS175E CRLS200E CRLS220E CRLS240E CRLS260E CRLS280E CRLS300E CRLS325E CRLS350E CRLS400E CRLS450E CRLS500E	CREAFORM® SILICONE GEL-FILLED BREAST IMPLANTS	ROUND LOW (RL), SMOOTH (S), ELLIPSE 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	Device Name	Model, Type	Intended purpose per IFU	Classification
CRIMV150E CRIMV175E CRIMV200E CRIMV225E CRIMV250E CRIMV275E CRIMV300E CRIMV325E CRIMV350E CRIMV375E CRIMV400E CRIMV450E CRIMV500E	CREAFORM® SILICONE GEL-FILLED BREAST IMPLANTS	ROUND INTERMEDIATE (RI), MICRO- TEXTURING (MV), ELLIPSE 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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CRIS150E CRIS175E CRIS200E CRIS225E CRIS250E CRIS275E CRIS300E CRIS325E CRIS350E CRIS375E CRIS400E CRIS450E CRIS500E	CREAFORM® SILICONE GEL-FILLED BREAST IMPLANTS	ROUND INTERMEDIATE (RI), SMOOTH (S), ELLIPSE GEL	• breast reconstruction following a mastectomy, • aesthetic breast augmentation, • 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	Device Name	Model, Type	Intended purpose per IFU	Classification
CRHMOV125E CRHMOV150E CRHMOV175E CRHMOV200E CRHMOV225E CRHMOV250E CRHMOV275E CRHMOV300E CRHMOV325E CRHMOV350E CRHMOV375E CRHMOV400E CRHMOV425E CRHMOV450E CRHMOV500E CRHMOV550E CRHMOV600E CRHMOV650E CRHMOV700E	CREAFORM® SILICONE GEL-FILLED BREAST IMPLANTS	ROUND HIGH (RH), MICRO-TEXTURING (MV), ELLIPSE 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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EC Design-Examination Certificate

Supplementary Information to CE 669619

Issued To:

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

Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
CRVHVMV130E CRVHVMV160E CRVHVMV190E CRVHVMV220E CRVHVMV250E CRVHVMV280E CRVHVMV310E CRVHVMV340E CRVHVMV370E CRVHVMV400E CRVHVMV450E CRVHVMV500E CRVHVMV550E CRVHVMV600E CRVHVMV650E CRVHVMV700E CRVHVMV750E CRVHVMV800E CRVHVMV900E	CREAFORM® SILICONE GEL-FILLED BREAST IMPLANTS	ROUND VERY HIGH (RVH), MICRO-TEXTURING (MV), ELLIPSE 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	Device Name	Model, Type	Intended purpose per IFU	Classification
CRVHS130E CRVHS160E CRVHS190E CRVHS220E CRVHS250E CRVHS280E CRVHS310E CRVHS340E CRVHS370E CRVHS400E CRVHS450E CRVHS500E CRVHS550E CRVHS600E CRVHS650E CRVHS700E CRVHS750E CRVHS800E CRVHS900E	CREAFORM® SILICONE GEL-FILLED BREAST IMPLANTS	ROUND VERY HIGH (RVH), SMOOTH (S), ELLIPSE 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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BRLMV100 BRLMV125 BRLMV150 BRLMV175 BRLMV200 BRLMV220 BRLMV240 BRLMV260 BRLMV280 BRLMV300 BRLMV325 BRLMV350 BRLMV400 BRLMV450 BRLMV500	EUROMI BIOSCIENCES® 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

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
BRLS100 BRLS125 BRLS150 BRLS175 BRLS200 BRLS220 BRLS240 BRLS260 BRLS280 BRLS300 BRLS325 BRLS350 BRLS400 BRLS450 BRLS500	EUROMI BIOSCIENCES® 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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BRMMV100 BRMMV125 BRMMV150 BRMMV175 BRMMV200 BRMMV220 BRMMV240 BRMMV260 BRMMV280 BRMMV300 BRMMV325 BRMMV350 BRMMV375 BRMMV400 BRMMV450 BRMMV500 BRMMV550 BRMMV600 BRMMV650 BRMMV700	EUROMI BIOSCIENCES® SILICONE GEL-FILLED BREAST IMPLANTS	ROUND MEDIUM (RM), 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

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BRMS100 BRMS125 BRMS150 BRMS175 BRMS200 BRMS220 BRMS240 BRMS260 BRMS280 BRMS300 BRMS325 BRMS350 BRMS375 BRMS400 BRMS450 BRMS500 BRMS550 BRMS600 BRMS650 BRMS700	EUROMI BIOSCIENCES® SILICONE GEL-FILLED BREAST IMPLANTS	ROUND MEDIUM (RM), 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	Device Name	Model, Type	Intended purpose per IFU	Classification
BRIMV150 BRIMV175 BRIMV200 BRIMV225 BRIMV250 BRIMV275 BRIMV300 BRIMV325 BRIMV350 BRIMV375 BRIMV400 BRIMV450 BRIMV500	EUROMI BIOSCIENCES® SILICONE GEL-FILLED BREAST IMPLANTS	ROUND INTERMEDIATE (RI), 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

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BRIS150 BRIS175 BRIS200 BRIS225 BRIS250 BRIS275 BRIS300 BRIS325 BRIS350 BRIS375 BRIS400 BRIS450 BRIS500	EUROMI BIOSCIENCES® SILICONE GEL-FILLED BREAST IMPLANTS	ROUND INTERMEDIATE (RI), 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	Device Name	Model, Type	Intended purpose per IFU	Classification
BRHVM125 BRHVM150 BRHVM175 BRHVM200 BRHVM225 BRHVM250 BRHVM275 BRHVM300 BRHVM325 BRHVM350 BRHVM375 BRHVM400 BRHVM425 BRHVM450 BRHVM500 BRHVM550 BRHVM600 BRHVM650 BRHVM700	EUROMI BIOSCIENCES® SILICONE GEL-FILLED BREAST IMPLANTS	ROUND HIGH (RH), 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

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BRHS125 BRHS150 BRHS175 BRHS200 BRHS225 BRHS250 BRHS275 BRHS300 BRHS325 BRHS350 BRHS375 BRHS400 BRHS425 BRHS450 BRHS500 BRHS550 BRHS600 BRHS650 BRHS700	EUROMI BIOSCIENCES® SILICONE GEL-FILLED BREAST IMPLANTS	ROUND HIGH (RH), 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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BRVHS130 BRVHS160 BRVHS190 BRVHS220 BRVHS250 BRVHS280 BRVHS310 BRVHS340 BRVHS370 BRVHS400 BRVHS450 BRVHS500 BRVHS550 BRVHS600 BRVHS650 BRVHS700 BRVHS750 BRVHS800 BRVHS900	EUROMI BIOSCIENCES® SILICONE GEL-FILLED BREAST IMPLANTS	ROUND VERY HIGH (RVH), 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	Device Name	Model, Type	Intended purpose per IFU	Classification
BRLMV100+ BRLMV125+ BRLMV150+ BRLMV175+ BRLMV200+ BRLMV220+ BRLMV240+ BRLMV260+ BRLMV280+ BRLMV300+ BRLMV325+ BRLMV350+ BRLMV400+ BRLMV450+ BRLMV500+	EUROMI BIOSCIENCES® SILICONE GEL-FILLED BREAST IMPLANTS	ROUND LOW (RL), 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

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BRLS100+ BRLS125+ BRLS150+ BRLS175+ BRLS200+ BRLS220+ BRLS240+ BRLS260+ BRLS280+ BRLS300+ BRLS325+ BRLS350+ BRLS400+ BRLS450+ BRLS500+	EUROMI BIOSCIENCES® SILICONE GEL-FILLED BREAST IMPLANTS	ROUND LOW (RL), SMOOTH (S), 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

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BRMMV100+ BRMMV125+ BRMMV150+ BRMMV175+ BRMMV200+ BRMMV220+ BRMMV240+ BRMMV260+ BRMMV280+ BRMMV300+ BRMMV325+ BRMMV350+ BRMMV375+ BRMMV400+ BRMMV450+ BRMMV500+ BRMMV550+ BRMMV600+ BRMMV650+ BRMMV700+	EUROMI BIOSCIENCES® SILICONE GEL-FILLED BREAST IMPLANTS	ROUND MEDIUM (RM), 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

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BRIMV150+ BRIMV175+ BRIMV200+ BRIMV225+ BRIMV250+ BRIMV275+ BRIMV300+ BRIMV325+ BRIMV350+ BRIMV375+ BRIMV400+ BRIMV450+ BRIMV500+	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

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BRHVM125+ BRHVM150+ BRHVM175+ BRHVM200+ BRHVM225+ BRHVM250+ BRHVM275+ BRHVM300+ BRHVM325+ BRHVM350+ BRHVM375+ BRHVM400+ BRHVM425+ BRHVM450+ BRHVM500+ BRHVM550+ BRHVM600+ BRHVM650+ BRHVM700+	EUROMI BIOSCIENCES® 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

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Date: **2021-04-02**

Expiry Date: **2024-05-26**

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Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

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EC Design-Examination Certificate

Supplementary Information to CE 669619

Issued To:

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

Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
BRHS125+ BRHS150+ BRHS175+ BRHS200+ BRHS225+ BRHS250+ BRHS275+ BRHS300+ BRHS325+ BRHS350+ BRHS375+ BRHS400+ BRHS425+ BRHS450+ BRHS500+ BRHS550+ BRHS600+ BRHS650+ BRHS700+	EUROMI BIOSCIENCES® SILICONE GEL-FILLED BREAST IMPLANTS	ROUND HIGH (RH) SMOOTH (S) 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

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BRVHVMV130+ BRVHVMV160+ BRVHVMV190+ BRVHVMV220+ BRVHVMV250+ BRVHVMV280+ BRVHVMV310+ BRVHVMV340+ BRVHVMV370+ BRVHVMV400+ BRVHVMV450+ BRVHVMV500+ BRVHVMV550+ BRVHVMV600+ BRVHVMV650+ BRVHVMV700+ BRVHVMV750+ BRVHVMV800+ BRVHVMV900+	EUROMI BIOSCIENCES® SILICONE GEL-FILLED BREAST IMPLANTS	ROUND VERY HIGH (RVH), 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

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
BRLMV100E BRLMV125E BRLMV150E BRLMV175E BRLMV200E BRLMV220E BRLMV240E BRLMV260E BRLMV280E BRLMV300E BRLMV325E BRLMV350E BRLMV400E BRLMV450E BRLMV500E	EUROMI BIOSCIENCES® SILICONE GEL-FILLED BREAST IMPLANTS	ROUND LOW (RL), MICRO-TEXTURING (MV), ELLIPSE 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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BRLS100E BRLS125E BRLS150E BRLS175E BRLS200E BRLS220E BRLS240E BRLS260E BRLS280E BRLS300E BRLS325E BRLS350E BRLS400E BRLS450E BRLS500E	EUROMI BIOSCIENCES® SILICONE GEL-FILLED BREAST IMPLANTS	ROUND LOW (RL), SMOOTH (S), ELLIPSE 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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BRMMV100E BRMMV125E BRMMV150E BRMMV175E BRMMV200E BRMMV220E BRMMV240E BRMMV260E BRMMV280E BRMMV300E BRMMV325E BRMMV350E BRMMV375E BRMMV400E BRMMV450E BRMMV500E BRMMV550E BRMMV600E BRMMV650E BRMMV700E	EUROMI BIOSCIENCES® SILICONE GEL-FILLED BREAST IMPLANTS	ROUND MEDIUM (RM), MICRO-TEXTURING (MV), ELLIPSE 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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BRMS100E BRMS125E BRMS150E BRMS175E BRMS200E BRMS220E BRMS240E BRMS260E BRMS280E BRMS300E BRMS325E BRMS350E BRMS375E BRMS400E BRMS450E BRMS500E BRMS550E BRMS600E BRMS650E BRMS700E	EUROMI BIOSCIENCES® SILICONE GEL-FILLED BREAST IMPLANTS	ROUND MEDIUM (RM), SMOOTH (S), ELLIPSE 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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BRIMV150E BRIMV175E BRIMV200E BRIMV225E BRIMV250E BRIMV275E BRIMV300E BRIMV325E BRIMV350E BRIMV375E BRIMV400E BRIMV450E BRIMV500E	EUROMI BIOSCIENCES® SILICONE GEL-FILLED BREAST IMPLANTS	ROUND INTERMEDIATE (RI), MICRO- TEXTURING (MV), ELLIPSE 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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Certificate History

Date	Reference Number	Action
Current	8694762	Issued.

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