

Declaration of Conformity

This European Declaration of Conformity is issued under the sole responsibility of the manufacturer.

MANUFACTURER		
Name of Company	Address	SRN
The Marena Group, LLC	650 Progress Industrial Blvd Lawrenceville, GA 30043-4866 United States	N/A

AUTHORIZED REPRESENTATIVE			
Name of Company	Address	SRN	Telephone/fax/email
Emergo Europe	Prinsessegracht 20 2514 AP The Hague The Netherlands	NL-AR-000000116	+31.70.345.8570 - phone EmergoEurope@ul.com

PRODUCT IDENTIFICATION		
Product Name	Product Code / Catalog Number	Basic UDI-DI
Marena Recovery Compression Products Marena Shape Compression Products Marena Sports Compression Products	See Attachment 1	1210001065030043BX

Intended Purpose
<p>Marena® compression products are intended for use to support and compress an area of the patient's body after the following surgeries.</p> <p>Surgical procedures for the breasts, including:</p> <ul style="list-style-type: none"> • Breast augmentation • Breast reduction • Breast reconstruction • Mastectomy • Mastopexy (breast lift) <p>Liposuction Lipoplasty Lipoinjection Brachioplasty Abdominoplasty Abdominal surgeries, including:</p> <ul style="list-style-type: none"> • Hysterectomy • Appendectomy • Caesarian section <p>Gynecomastia Facial and oral/maxillofacial surgeries</p>

RISK CLASS FOR MEDICAL DEVICES	
Device Classification	Common Specifications
Class I Self Certified Rule 4	N/A

The Marena Group, LLC declares that the above-mentioned products meet the provision of the following EU legislation:

- Medical Devices Regulation (EU) 2017/745

COMPANY REPRESENTATIVE: William Pembroke

TITLE: CFO

SIGNATURE:



PLACE: Lawrenceville, GA
United States

DATE: 23/04/2021

Attachment 1

Compression Garment Marena Recovery: 4DFB
Compression Garment Marena Recovery: 4DFV
Compression Garment Marena Recovery: 4DMB
Compression Garment Marena Recovery: 4DMV
Compression Garment Marena Recovery: 804ZP
Compression Garment Marena Recovery: AB3
Compression Garment Marena Recovery: AB3F7
Compression Garment Marena Recovery: AB3S3
Compression Garment Marena Recovery: AB3X
Compression Garment Marena Recovery: AB4
Compression Garment Marena Recovery: AB4F7
Compression Garment Marena Recovery: AB4S2
Compression Garment Marena Recovery: AB4X
Compression Garment Marena Recovery: B
Compression Garment Marena Recovery: B/ISB
Compression Garment Marena Recovery: B01G
Compression Garment Marena Recovery: B01GP
Compression Garment Marena Recovery: B09Z
Compression Garment Marena Recovery: B11
Compression Garment Marena Recovery: B15
Compression Garment Marena Recovery: B16
Compression Garment Marena Recovery: B16P
Compression Garment Marena Recovery: B19
Compression Garment Marena Recovery: B2
Compression Garment Marena Recovery: B2P
Compression Garment Marena Recovery: BA
Compression Garment Marena Recovery: BB
Compression Garment Marena Recovery: BNRZ
Compression Garment Marena Recovery: BNVL
Compression Garment Marena Recovery: BR
Compression Garment Marena Recovery: BT-LGA2
Compression Garment Marena Recovery: BW-9
Compression Garment Marena Recovery: BW-9-W
Compression Garment Marena Recovery: CABGV
Compression Garment Marena Recovery: C-FBCS
Compression Garment Marena Recovery: C-SFBHS2
Compression Garment Marena Recovery: EF-B01G
Compression Garment Marena Recovery: EF-B15
Compression Garment Marena Recovery: FBA
Compression Garment Marena Recovery: FBA2
Compression Garment Marena Recovery: FBBA
Compression Garment Marena Recovery: FBBL
Compression Garment Marena Recovery: FBBM
Compression Garment Marena Recovery: FBBMSM

Compression Garment Marena Recovery: FTRS/SM
Compression Garment Marena Recovery: FTS
Compression Garment Marena Recovery: FV2L
Compression Garment Marena Recovery: FV2M
Compression Garment Marena Recovery: FVL
Compression Garment Marena Recovery: FVM
Compression Garment Marena Recovery: FVMK
Compression Garment Marena Recovery: FVNS
Compression Garment Marena Recovery: FVNSP
Compression Garment Marena Recovery: FVNSZ
Compression Garment Marena Recovery: FVOM
Compression Garment Marena Recovery: GFBRT2
Compression Garment Marena Recovery: GFVM
Compression Garment Marena Recovery: HB01
Compression Garment Marena Recovery: ISB
Compression Garment Marena Recovery: ISB-05
Compression Garment Marena Recovery: ISB2
Compression Garment Marena Recovery: ISBX
Compression Garment Marena Recovery: LGA
Compression Garment Marena Recovery: LGA2
Compression Garment Marena Recovery: LGL
Compression Garment Marena Recovery: LGL2
Compression Garment Marena Recovery: LGM
Compression Garment Marena Recovery: LGM2
Compression Garment Marena Recovery: LGS
Compression Garment Marena Recovery: LGS2
Compression Garment Marena Recovery: LGS-SZ
Compression Garment Marena Recovery: LGT
Compression Garment Marena Recovery: LGT2
Compression Garment Marena Recovery: LL1GL
Compression Garment Marena Recovery: LL1GM
Compression Garment Marena Recovery: LL1GS
Compression Garment Marena Recovery: LW-LGA
Compression Garment Marena Recovery: LW-LGA2
Compression Garment Marena Recovery: LW-LGL
Compression Garment Marena Recovery: LW-LGL2
Compression Garment Marena Recovery: LW-LGM
Compression Garment Marena Recovery: LW-LGM2
Compression Garment Marena Recovery: LW-LGS
Compression Garment Marena Recovery: LW-LGS2
Compression Garment Marena Recovery: MB
Compression Garment Marena Recovery: MB/SS
Compression Garment Marena Recovery: MB2
Compression Garment Marena Recovery: MBL
Compression Garment Marena Recovery: MCV/SS
Compression Garment Marena Recovery: MG

Compression Garment Marena Recovery: MGL
Compression Garment Marena Recovery: MGS
Compression Garment Marena Recovery: MHB2
Compression Garment Marena Recovery: MHTT
Compression Garment Marena Recovery: MHV
Compression Garment Marena Recovery: MHV/SS
Compression Garment Marena Recovery: MTT
Compression Garment Marena Recovery: MV
Compression Garment Marena Recovery: MV/SS
Compression Garment Marena Recovery: MVS
Compression Garment Marena Recovery: POUCH
Compression Garment Marena Recovery: POUCH2
Compression Garment Marena Recovery: PPGA
Compression Garment Marena Recovery: PPGS
Compression Garment Marena Recovery: SBBS2
Compression Garment Marena Recovery: SFBHA
Compression Garment Marena Recovery: SFBHA2
Compression Garment Marena Recovery: SFBHL
Compression Garment Marena Recovery: SFBHL2
Compression Garment Marena Recovery: SFBHM
Compression Garment Marena Recovery: SFBHM2
Compression Garment Marena Recovery: SFBHRA
Compression Garment Marena Recovery: SFBHRA2
Compression Garment Marena Recovery: SFBHRL
Compression Garment Marena Recovery: SFBHRL2
Compression Garment Marena Recovery: SFBHRM
Compression Garment Marena Recovery: SFBHRM2
Compression Garment Marena Recovery: SFBHRS
Compression Garment Marena Recovery: SFBHRS2
Compression Garment Marena Recovery: SFBHS
Compression Garment Marena Recovery: SFBHS2
Compression Garment Marena Recovery: SFBHT
Compression Garment Marena Recovery: SL
Compression Garment Marena Recovery: SM
Compression Garment Marena Recovery: SPAD
Compression Garment Marena Recovery: UV/CP
Compression Garment Marena Shape: ME-1000
Compression Garment Marena Shape: ME-1001
Compression Garment Marena Shape: ME-210
Compression Garment Marena Shape: ME-211
Compression Garment Marena Shape: ME-221
Compression Garment Marena Shape: ME-222
Compression Garment Marena Shape: ME-300
Compression Garment Marena Shape: ME-320
Compression Garment Marena Shape: ME-321
Compression Garment Marena Shape: ME-400

Compression Garment Marena Shape: ME-420
Compression Garment Marena Shape: ME-421
Compression Garment Marena Shape: ME-500
Compression Garment Marena Shape: ME-501
Compression Garment Marena Shape: ME-520
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Compression Garment Marena Shape: ME-611
Compression Garment Marena Shape: ME-620
Compression Garment Marena Shape: ME-621
Compression Garment Marena Shape: ME-802
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Compression Garment Marena Shape: ME-806
Compression Garment Marena Shape: ME-807
Compression Garment Marena Shape: VA-01
Compression Garment Marena Shape: VA-02
Compression Garment Marena Shape: VA-03
Compression Garment Marena Sport: 100
Compression Garment Marena Sport: 103
Compression Garment Marena Sport: 104
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Compression Garment Marena Sport: 202
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Compression Garment Marena Sport: 625
Compression Garment Marena Sport: 626
Compression Garment Marena Sport: 802
Compression Garment Marena Sport: 803

Compression Garment Marena Sport: 812
Compression Garment Marena Sport: 100Z
Compression Garment Marena Sport: 100ZP
Compression Garment Marena Sport: A8-001