

Declaration of Conformity Certificate

Manufacturer Name: PolyGel, LLC
Manufacturer Address: 30 Leslie Court
 Whippany, NJ 07981 USA
 +1 (973) 884-8995
Single Registration Number: US-MF-000008436
EU Authorized Representative: QualRep Services BV
EU AR Address: Utrechtseweg 310 – B42
 6812 AR, Arnhem, The Netherlands

Basic UDI-DI(s) and Product Identification (see Attachment for list of all products):


EMDN Code	EMDN Description	Internal Product Family Names	Basic UDI-DI's
Z120602	Physiotherapy Equipment	Hot-Cold Therapy Pack, Reusable, Gel	081110001HOTCOLDGEL8D
Z120602	Physiotherapy Equipment	Hot-Cold Therapy Pack, Reusable, Silica	081110001HOTCOLDSILICA39
Z120602	Physiotherapy Equipment	Hot-Cold Therapy Pack, Reusable, Gel, Chemo	081110001CHEMOM4
Z120602	Physiotherapy Equipment	Eye Heat Therapy Pack	081110001EYEHEATT4

Intended Purpose: *PolyGel Hot/Cold Therapy Devices* are intended to be used to provide cold or heat therapy to specific body parts to support healing post-injury, surgery and/or chronic pain.
Risk Classification: Class 1 per Rule 1 – Non-invasive device
Notified Body: Not applicable
Expiration Date: Not applicable
Common Specification(s): Not applicable
Conformity Assessment Route: PolyGel, LLC uses the following for the CE-labeling of their products according to the Regulation MDR 2017/745:
Class I; EC conformity declaration according to Annex I, Annex II and Annex III

This declaration of conformity is issued under the sole responsibility of PolyGel, LLC. We hereby declare that the medical device(s) specified above meet the provision of the Regulation (EU) MDR 2017/745 for medical devices. PolyGel, LLC will follow Annexes II and III of the MDR (2017/745). All supporting documentation is retained at the premises of the manufacturer.

The product(s) identified above meet requirements of the Medical Devices Regulation by meeting the following standards:

Standard No.	Standard Description
2017/745	EU Medical Device Regulation
ISO 14791:2019	Medical devices – Application of risk management to medical devices
ISO / TR 24791:2020	Medical devices – Guidance on the application of ISO 14791
ISO /DIS 15223-1	Medical devices – symbols to be used with medical device labels, labelling and information to be supplied – Part I: General requirements
EN 1041:2008	Information supplied by the manufacturer of medical devices
DIS EN ISO 20417	Information supplied by the manufacturer of medical devices
ISO 14155:2011	Clinical investigation of medical devices for human subjects – Good clinical practice
MEDDEV 2.7/1: Rev 4 June 2016	Evaluation of Clinical Data: A Guide For Manufacturers And Notified Bodies
207/2012	Commission Regulation on electronic instructions for use of medical devices
ISO 10993-1:2018	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process

Signature: _____ Place and date (DD-MM-YYYY) of issue: _____
 Lawrence Kersen, Chairman  _____ Whippany, NJ USA. _____

Attachment to Declaration of Conformity:

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EMDN Code: Z120602 Physiotherapy

Reference Number	Description	UDI-DI (Each)	UDI-DI (Case)	Basic UDI-DI
760-02NC1	ADVANCED COOLING GEL SLIPPER, PR – SM	00810001501242	10810001501249	081110001CHEMOM4
760-04NC1	ADVANCED COOLING GEL SLIPPER, PR – LG	00810001502249	10810001502246	081110001CHEMOM4
761-00NC1	ADVANCED COOLING GEL MITTS - 1 PR	00810001501013	10810001501010	081110001CHEMOM4
762-00NC1	ADVANCED COOLING GEL CAP	00810001501228	10810001501225	081110001CHEMOM4
416SB-RET	WARMING EYE MASK – SILICA BEAD	00810001500788	10810001500785	081110001EYEHEATT4
417SB-RET	DRY EYE MOISTURE HOT/COLD MASK – SILICA BEAD	00810001500795	10810001500792	081110001EYEHEATT4
EU416SBNC1	WARMING EYE MASK – SILICA BEAD	01220000242456	11220000242453	081110001EYEHEATT4
EU417SBNC1	DRY EYE MOISTURE HOT/COLD MASK – SILICA BEAD	01220000242463	11220000242460	081110001EYEHEATT4
EU418SB-RET	HIGH NECK WARMING SHOULDER WRAP	01220000242586	10810001502161	081110001EYEHEATT4
6022	KNEE COLD & HOT THERAPY DEVICE	00810001502164	10811100015231	081110001HOTCOLDGEL8D
6023	KNEE COLD & HOT THERAPY DEVICE – LARGE	00811100015234	10810001500594	081110001HOTCOLDGEL8D
6022 GP	KNEE COLD & HOT THERAPY GEL PACK	00810001500597	10810001501775	081110001HOTCOLDGEL8D
6022 NS	KNEE COLD & HOT THERAPY DEVICE	00810001501778	10810001502215	081110001HOTCOLDGEL8D
6023 GP	KNEE COLD & HOT THERAPY GEL PACK – LARGE	00810001502218	10811100019444	081110001HOTCOLDGEL8D
6032 GP	SHOULDER COLD & HOT THERAPY GEL PACK	00810001501082	10811100018577	081110001HOTCOLDGEL8D
6032 NS	UNIVERSAL SHOULDER COLD & HOT THERAPY DEVICE	00811100018570	00810001500375	081110001HOTCOLDGEL8D
6300-COLD	THE MOST FLEXIBLE GEL COLD PACK – STANDARD	00811100010741	10811100018416	081110001HOTCOLDGEL8D
6300-COLD-2PK	THE MOST FLEXIBLE GEL COLD PACK – STANDARD 2PK	00811100018419	10811100019475	081110001HOTCOLDGEL8D
6300-COLD-STRAP	STANDARD COLD GEL PACK WITH STRAPS	00811100019478	10810001501522	081110001HOTCOLDGEL8D
6300-STRAP-2PK	COLD THERAPY GEL PACK, STANDARD, WITH STRAPS – 2/PK	00810001501525	10811100010755	081110001HOTCOLDGEL8D
6301-COLD	THE MOST FLEXIBLE GEL COLD PACK – NECK CONTOUR	00811100010758	10811100019451	081110001HOTCOLDGEL8D
6301-COLD-STRAP	NECK CONTOUR COLD GEL PACK WITH STRAPS	00811100019454	10811100010762	081110001HOTCOLDGEL8D
6302-COLD	THE MOST FLEXIBLE GEL COLD PACK – OVERSIZE	00811100010765	10811100010779	081110001HOTCOLDGEL8D
6303-COLD	THE MOST FLEXIBLE GEL COLD PACK – HALF SIZE	00811100010772	10811100019895	081110001HOTCOLDGEL8D
6303-COLD-2PK	THE MOST FLEXIBLE GEL COLD PACK - HALF SIZE 2PK	00811100019898	10811100019468	081110001HOTCOLDGEL8D
6303-COLD-STRAP	HALF COLD GEL PACK WITH STRAPS	00811100019461	10810001501652	081110001HOTCOLDGEL8D
6304-STRAP4PK	4” ROUND COLD GEL PACK – W/STRAPS – 4 PK	00810001501655	50810001501643	081110001HOTCOLDGEL8D
6304-TA4-2PK	4” ROUND COLD GEL PACK – 2 PK	00810001501648	10810001500655	081110001HOTCOLDGEL8D
700-02RET	COLD SLEEVE – S	00810001500658	10810001500662	081110001HOTCOLDGEL8D
700-03RET	COLD SLEEVE – M	00810001500665	10810001500679	081110001HOTCOLDGEL8D
700-04RET	COLD SLEEVE – L	00810001500672	10811100014555	081110001HOTCOLDGEL8D
715 CAT	UNIVERSAL COLD & HOT WRAP	00811100014558	10810001500099	081110001HOTCOLDGEL8D
715-20CAT2PK	UNIVERSAL HOT AND COLD WRAP – WITH 20” STRAP – 2/PK	00810001500092	10811100017228	081110001HOTCOLDGEL8D
716 CAT	UNIVERSAL COLD PACK WRAP	00811100017221	10811100019796	081110001HOTCOLDGEL8D
716 CAT-2GP	UNIVERSAL COLD PACK WRAP – WITH 2 GEL PACKS	00811100019799	10810001501577	081110001HOTCOLDGEL8D
716 RET-2PK	UNIVERSAL COLD PACK WRAP 10”X5” – 2 PK	00810001501570	10811100019901	081110001HOTCOLDGEL8D
717-RET	DELUXE UNIVERSAL COLD PACK	00811100019904	10810001502062	081110001HOTCOLDGEL8D
780-00NC4	COOLING GEL BREAST PACK – 1 PR	00810001502065	10810001502079	081110001HOTCOLDGEL8D
781-00NC4	WARMING GEL BREAST PACK – 1 PR	00810001502072	10810001502086	081110001HOTCOLDGEL8D
782-00NC6	COOLING PERINEAL PACK – 1 PC	00810001502089	11220000240428	081110001HOTCOLDGEL8D
EU6300-TACOLD1	STANDARD COLD PACK	01220000240421	11220000240411	081110001HOTCOLDGEL8D
EU6301-TACOLD1	NECK COLD PACK	01220000240414	11220000240435	081110001HOTCOLDGEL8D
EU6302-TACOLD1	OVERSIZE COLD PACK	01220000240438	11220000240442	081110001HOTCOLDGEL8D
EU6303-TACOLD1	HALFSIZE COLD PACK	01220000240445	11220000242538	081110001HOTCOLDGEL8D
EU6304-TA4-2	4” ROUND COLD GEL PACK – 2 PK	01220000242531	11220000242477	081110001HOTCOLDGEL8D
EU700-02NC1	COLD SLEEVE – S	01220000242470	11220000242484	081110001HOTCOLDGEL8D
EU700-03NC1	COLD SLEEVE – M	01220000242487	11220000242613	081110001HOTCOLDGEL8D
EU700-04NC1	COLD SLEEVE – L	01220000242616	11220000242491	081110001HOTCOLDGEL8D
EU717-NC1	DELUXE UNIVERSAL COLD PACK	01220000242494	10811100017457	081110001HOTCOLDGEL8D
GP23-24	REPLACEMENT COLD GEL PACKS FOR FOOT COLD THERAPY RELIEF DEVICES – HALF & FULL SIZE (2/EA)	00811100017450	10810001500273	081110001HOTCOLDGEL8D
GP30-00BLU10PK	4” CIRCLE GEL COLD PACK – 10/PK	00810001500276	00810001502379	081110001HOTCOLDGEL8D
GP30-00BLU5PK	4” CIRCLE GEL COLD PACK - 5/PK	00810001500214	10810001500815	081110001HOTCOLDGEL8D
409SB-RET	MOIST HEAT LONG-LASTING SHOULDER - SILICA BEAD	00810001500818	10810001500808	081110001HOTCOLDSILICA39
410SB-RET	INTENSE MOISTURE SHOULDER WRAP - SILICA BEAD	00810001500801	10810001500730	081110001HOTCOLDSILICA39
411-SB-RET	WARMING NECK WRAP – SILICA BEAD	00810001500733	10810001501836	081110001HOTCOLDSILICA39
416SB-RET	WARMING EYE MASK - SILICA BEAD	00810001500788	10810001500785	081110001HOTCOLDSILICA39
417SB-RET	DRY EYE MOISTURE HOT/COLD MASK - SILICA BEAD	00810001500795	10810001500792	081110001HOTCOLDSILICA39

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Reference Number	Description	UDI-DI (Each)	UDI-DI (Case)	Basic UDI-DI
418SB-RET	HIGH NECK WARMING SHOULDER WRAP - SILICA BEAD	00810001501839	11220000242422	081110001HOTCOLDSILICA39
EU409SBNC1	SHOULDER MOIST HEAT LONG-LASTING - SILICA BEAD	01220000242425	11220000242439	081110001HOTCOLDSILICA39
EU410SBNC1	INTENSE MOISTURE SHOULDER WRAP - SILICA BEAD	01220000242432	11220000242446	081110001HOTCOLDSILICA39
EU411SBNC1	WARMING NECK WRAP - SILICA BEAD	01220000242449	11220000242583	081110001HOTCOLDSILICA39
EU706-02NC1	Headache Relief Cap (S/M)	01220000242777	1081000150233	081110001HOTCOLDGEL8D
EU706-04NC1	Headache Relief Cap (L/XL)	01220000242753	10810001502345	081110001HOTCOLDGEL8D
EU760-02NC1	Advanced Cooling Gel Slippers (S/M)	01220000242968	10810001501249	081110001HOTCOLDGEL8D
EU760-04NC1	Advanced Cooling Gel Slippers (L/XL)	01220000242975	10810001502246	081110001HOTCOLDGEL8D
EU761-00NC1	Advanced Cooling Gel Mitts	01220000242982	10810001501010	081110001HOTCOLDGEL8D
EU762-00NC1	Advanced Cooling Gel Cap	01220000242999	10810001501225	081110001HOTCOLDGEL8D
EU780-00NC4	Breastfeeding Relief Gel Pack W/Cold Therapy	01220000242937	10810001502062	081110001HOTCOLDSILICA39
EU781-00NC4	Breastfeeding Relief Pack W/Moist Heat Therapy	01220000242944	10810001502079	081110001HOTCOLDGEL8D
EU782-00NC6	Postpartum Gel Cold Pack	01220000242951	10810001502086	081110001HOTCOLDGEL8D
EU419SB-00NC1	Low Back Silica Wrap	01220000243033	10810001502383	081110001HOTCOLDSILICA39