

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/CND Code	EMDN/CND Description	Internal Product Family Names	Basic UDI-DI's
Y061203	ORTHOSIS, FOOT (INCLUDING INSOLES AND INSERTS)	Foot - Toe Protector	081110001FOOTTOEPROTEM
Y061203	ORTHOSIS, FOOT (INCLUDING INSOLES AND INSERTS)	Orthotic Insole, Prefab, Non-Antimicrobial	081110001ORTHINS4L
Y061203	ORTHOSIS, FOOT (INCLUDING INSOLES AND INSERTS)	Toe Separators	081110001TOESEPUG
Y061203	ORTHOSIS, FOOT (INCLUDING INSOLES AND INSERTS)	Hallux Valgus Orthosis	081110001HALVALL6
Y061203	ORTHOSIS, FOOT (INCLUDING INSOLES AND INSERTS)	Flat Foot Correction Sock	081110001FLATSOCK4D

Intended Purpose: *PolyGel Gel Medical Footcare Products* are intended to be used to minimize discomfort, pressure, friction and relieve pressure related to various temporary and chronic foot ailments.

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 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

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Signature:

Place and date (DD-MM-YYYY) of issue:

Lawrence Kersen

Whippany, NJ USA 15-07-2021

Lawrence Kersen, Chairman

Declaration of Conformity Certificate

Attachment to Declaration of Conformity:

EMDN/CND Code: Y061203 ORTHOSIS, FOOT (INCLUDING INSOLES AND INSERTS)

Reference Number	Description	UDI-DI	Basic UDI-DI
1000-M NCBC12PK	NatraCure® M-Gel CORN PAD, 12 PCS, ONE SIZE	00811100018341	081110001FOOTTOEPROTEM
1000-M NCBC24PK	NatraCure® M-Gel CORN PAD, 24 PCS. ONE SIZE	00810001500993	081110001FOOTTOEPROTEM
10015-M-00CAT	NatraCure® T-Gel ALL GEL FOOTIES, 1 PR, WM 7-10, MN 5-9	00810001500283	081110001FOOTTOEPROTEM
10015-M-00RET	NatraCure® T-Gel ALL GEL FOOTIES, 1 PR, WM 7-10, MN 5-9	00811100018112	081110001FOOTTOEPROTEM
10016-M-02-RET	NatraCure® T-Gel ALL GEL OPEN TOE FOOT SLEEVE, SM	00811100018754	081110001FOOTTOEPROTEM
10016-M-03-RET	NatraCure® T-Gel ALL GEL OPEN TOE FOOT SLEEVE, MD	00811100018761	081110001FOOTTOEPROTEM
10017-M-02-RET	NatraCure® T-Gel ALL GEL TOE PROTECTOR, SM	00811100018778	081110001FOOTTOEPROTEM
10017-M-03-RET	NatraCure® T-Gel ALL GEL TOE PROTECTOR, MD	00811100018785	081110001FOOTTOEPROTEM
1050-M NCBC 6PK	NatraCure® M-Gel FULLY GEL LINED TOE PROTECTORS, 6 PCS, ONE SIZE	00811100018365	081110001FOOTTOEPROTEM
1075-M RET6PK	NatraCure® M2-Gel ALL GEL TOE/FINGER CAP, 6 PCS, SM-MD	00811100019522	081110001FOOTTOEPROTEM
1076-M/BLUE6PK	NatraCure® M2-Gel ALL GEL TOE/FINGER CAP, 6 PCS, SM-MD	00810001501600	081110001FOOTTOEPROTEM
1200-M NCBC5PK	NatraCure® M-Gel COATED DIGITAL TUBES, 5 PCS, NARROW	00811100018433	081110001FOOTTOEPROTEM
1297-S CAT	NatraCure® S-Gel GEL METATARSAL WRAP, LG-XL	00811100015975	081110001FOOTTOEPROTEM
1314-M CAT	NatraCure® T-Gel TWO IN ONE MET PROTECTOR WITH SEPARATOR, SM-MD	00811100047832	081110001FOOTTOEPROTEM
1314-M-00RET	NatraCure® T-Gel TWO IN ONE MET PROTECTOR WITH SEPARATOR, SM-MD	00811100018792	081110001FOOTTOEPROTEM
1401-MBFITCAT	NatraCure® M-Gel ACHILLES PROTECTION SLEEVE, ONE SIZE	00811100017955	081110001FOOTTOEPROTEM
2133/34-T CAT	NatraCure® T-Gel SANDAL SPREADER W/BALL OF FOOT CUSHION, PAIR	00811100017207	081110001FOOTTOEPROTEM
EU1000-MGS4	GelSmart® M-Gel CORN PADS, 4 PCS, ONE SIZE	01220000240797	081110001FOOTTOEPROTEM
EU1000-MNCBC2	NatraCure® M-Gel CORN PADS, 2 PCS, ONE SIZE	01220000240018	081110001FOOTTOEPROTEM
EU1001-MGS4	GelSmart® M-Gel CORN PADS, LG-XL	01220000240803	081110001FOOTTOEPROTEM
EU10015-M00NC1	NatraCure® T-Gel ALL GEL FOOTIES, 1 PR, WM 7-10; MN 5-9	01220000240193	081110001FOOTTOEPROTEM
EU10016-M02NC1	NatraCure® T-Gel ALL GEL OPEN TOE FOOT SLEEVE, SM	01220000240278	081110001FOOTTOEPROTEM
EU10016-M03NC1	NatraCure® T-Gel ALL GEL OPEN TOE FOOT SLEEVE, MD	01220000240285	081110001FOOTTOEPROTEM
EU10017-M02NC1	NatraCure® T-Gel ALL GEL TOE PROTECTOR, SM	01220000240254	081110001FOOTTOEPROTEM
EU10017-M03NC1	NatraCure® T-Gel ALL GEL TOE PROTECTOR, MD	01220000240261	081110001FOOTTOEPROTEM
EU1010-MGS3	GelSmart® M-Gel ROLLED DIGITAL PADS, MINI	01220000240834	081110001FOOTTOEPROTEM
EU1011-MGS3	GelSmart® M-Gel ROLLED DIGITAL PADS, SM/MED	01220000240841	081110001FOOTTOEPROTEM
EU1012-MGS3	GelSmart® M-Gel ROLLED DIGITAL PADS, LG/XLG	01220000240858	081110001FOOTTOEPROTEM
EU1013-MGS3	GelSmart® M-Gel ROLLED DIGITAL PADS, XXL	01220000240865	081110001FOOTTOEPROTEM
EU1026-MGS3	GelSmart® M-Gel ALL GEL LITTLE TOE SLEEVE, ONE SIZE	01220000240872	081110001FOOTTOEPROTEM
EU1026-MNCBC2	NatraCure® M-Gel ALL GEL LITTLE TOE SLEEVE, ONE SIZE	01220000240131	081110001FOOTTOEPROTEM
EU1027-MGS3	GelSmart® M2-Gel ALL GEL TOE/FINGER TUBE, SM	01220000240889	081110001FOOTTOEPROTEM
EU1028-MGS3	GelSmart® M2-Gel ALL GEL TOE/FINGER TUBE, MD	01220000240896	081110001FOOTTOEPROTEM
EU1029-MGS3	GelSmart® M2-Gel ALL GEL TOE/FINGER TUBE, LG	01220000240902	081110001FOOTTOEPROTEM
EU1050-MGS3	GelSmart® M-Gel FULLY GEL LINED TOE PROTECTORS, 3 PCS, SM/MD	01220000241114	081110001FOOTTOEPROTEM
EU1051-MGS3	GelSmart® M-Gel FULLY GEL LINED TOE PROTECTORS, 3 PCS, LG/XL	01220000241121	081110001FOOTTOEPROTEM
EU1052-MGS3	GelSmart® M-Gel FULLY GEL LINED TOE PROTECTORS, 3 PCS, XXL	01220000241138	081110001FOOTTOEPROTEM
EU1056-MGS3	GelSmart® M-Gel GEL LINED MESH DIGITAL CAP, 3 PCS, SM/MD	01220000241145	081110001FOOTTOEPROTEM
EU1057-MGS3	GelSmart® M-Gel GEL LINED MESH DIGITAL CAP, 3 PCS, LG/XL	01220000241152	081110001FOOTTOEPROTEM
EU1058-MGS3	GelSmart® M-Gel GEL LINED MESH DIGITAL CAP, 3 PCS, XXL	01220000241169	081110001FOOTTOEPROTEM
EU1075-MGS4	GelSmart® M2-Gel ALL GEL TOE/FINGER CAPS, 4 PCS, SM-MD	01220000241176	081110001FOOTTOEPROTEM
EU1075-MNCBC1	NatraCure® M2-Gel ALL GEL TOE/FINGER CAP, ONE SIZE	01220000240032	081110001FOOTTOEPROTEM
EU1076-MGS4	GelSmart® M2-Gel ALL GEL TOE/FINGER CAPS, 4 PCS, LG/XL	01220000241183	081110001FOOTTOEPROTEM
EU1077-MGS4	GelSmart® M2-Gel ALL GEL TOE/FINGER CAPS, 4 PCS, XXL	01220000241190	081110001FOOTTOEPROTEM
EU1150-MGS1	GelSmart® M-Gel HALF COATED DIGITAL TUBE, SM/MD	01220000241343	081110001FOOTTOEPROTEM
EU1151-MGS1	GelSmart® M-Gel HALF COATED DIGITAL TUBE, LG/XL	01220000241350	081110001FOOTTOEPROTEM
EU1152-MGS1	GelSmart® M-Gel HALF COATED DIGITAL TUBE, MINI	01220000241367	081110001FOOTTOEPROTEM
EU1200-MGS2	GelSmart® M-Gel GEL COATED DIGITAL TUBE, 2 PCS, NARROW	01220000241381	081110001FOOTTOEPROTEM
EU1201-MGS2	GelSmart® M-Gel GEL COATED DIGITAL TUBE, 2 PCS, WIDE	01220000241398	081110001FOOTTOEPROTEM
EU1202-MGS2	GelSmart® M-Gel FULLY COATED DIGITAL MESH TUBES, 2 PCS, 152MM, NARROW	01220000241404	081110001FOOTTOEPROTEM
EU1204-MGS2	GelSmart® M-Gel FULLY COATED DIGITAL MESH TUBES, 2 PCS, 152MM, MD	01220000241428	081110001FOOTTOEPROTEM
EU1207-MGS2	GelSmart® M-Gel FULLY COATED DIGITAL MESH TUBES, 2 PCS, 152MM, WIDE	01220000241435	081110001FOOTTOEPROTEM
EU1225-MCGS1	GelSmart® M-Gel UNIVERSAL METATARSAL SLEEVE, 1 PC, SM/MD RT	01220000241442	081110001FOOTTOEPROTEM
EU1226-MCGS1	GelSmart® M-Gel UNIVERSAL METATARSAL SLEEVE, 1 PC, SM/MD LF	01220000241459	081110001FOOTTOEPROTEM
EU1227-MCGS1	GelSmart® M-Gel UNIVERSAL METATARSAL SLEEVE, 1 PC, LG/XL RT	01220000241466	081110001FOOTTOEPROTEM
EU1228-MCGS1	GelSmart® M-Gel UNIVERSAL METATARSAL SLEEVE, 1 PC, LG/XL LF	01220000241473	081110001FOOTTOEPROTEM
EU1275-MCGS2	GelSmart® M-Gel CGS THIN FOREFOOT GEL PAD, SM-MD	01220000241480	081110001FOOTTOEPROTEM
EU1276-MCGS2	GelSmart® M-Gel CGS THIN FOREFOOT GEL PAD, LG-XL	01220000241497	081110001FOOTTOEPROTEM

Declaration of Conformity Certificate

Reference Number	Description	UDI-DI	Basic UDI-DI
EU1295-SGS1	GelSmart® S-Gel METATARSAL WRAP, SM-MD	01220000241510	081110001FOOTTOEPROTEM
EU1297-SGS1	GelSmart® S-Gel METATARSAL WRAP, LG-XL	01220000241534	081110001FOOTTOEPROTEM
EU1314-M00NC2	NatraCure® T-Gel TWO IN ONE MET PROTECTOR WITH SEPARATOR, SM-MD	01220000241664	081110001FOOTTOEPROTEM
EU1322-SCNCCS1	NatraCure® S-Gel THIN FOREFOOT CUSHION, COVERED, SM LF	01220000240506	081110001FOOTTOEPROTEM
EU1324-SCNCCS1	NatraCure® S-Gel THIN FOREFOOT CUSHION, COVERED, LG LF	01220000240513	081110001FOOTTOEPROTEM
EU1326-SCGS2	GelSmart® S-Gel UNIVERSAL THIN FOREFOOT CUSHION, SM-MD	01220000241756	081110001FOOTTOEPROTEM
EU1327-SCGS2	GelSmart® S-Gel UNIVERSAL THIN FOREFOOT CUSHION, LG-XL	01220000241763	081110001FOOTTOEPROTEM
EU1342-MCGS2	GelSmart® M-Gel FOREFOOT PROTECTOR, MD	01220000241770	081110001FOOTTOEPROTEM
EU1343-MCGS2	GelSmart® M-Gel FOREFOOT PROTECTOR, LG	01220000241787	081110001FOOTTOEPROTEM
EU1400-MBFITGS1	GelSmart® M-Gel FITTED ACHILLES HEEL GEL PROECTION SLEEVE, SM/MD	01220000241817	081110001FOOTTOEPROTEM
EU1400MBFITCS1	NatraCure® M-Gel FITTED ACHILLES HEEL GEL PROTECTION SLEEVE, SM/MD	01220000240520	081110001FOOTTOEPROTEM
EU1401-MBFITGS1	GelSmart® M-Gel FITTED ACHILLES HEEL GEL PROTECTION SLEEVE, LG/XL	01220000241824	081110001FOOTTOEPROTEM
EU1404-MBFITGS1	GelSmart® M-Gel ANKLE PROTECTION SLEEVE, SM-MD	01220000241831	081110001FOOTTOEPROTEM
EU1405-MBFITGS1	GelSmart® M-Gel ANKLE PROTECTION SLEEVE, LG-XL	01220000241848	081110001FOOTTOEPROTEM
EU1406-MBFITGS1	GelSmart® M-Gel BLISTER PREVENTION SOCKS, SM-MD	01220000241855	081110001FOOTTOEPROTEM
EU1407-MBFITGS1	GelSmart® M-Gel BLISTER PREVENTION SOCKS, LG-XL	01220000241862	081110001FOOTTOEPROTEM
EU1408-MBFITGS1	GelSmart® M-Gel DORSUM PROTECTION SLEEVE, SM-MD	01220000241879	081110001FOOTTOEPROTEM
EU1409-MBFITGS1	GelSmart® M-Gel DORSUM PROTECTION SLEEVE, LG-XL	01220000241886	081110001FOOTTOEPROTEM
EU1411-M-00GS1	GelSmart® T-Gel ALL GEL HEEL SLEEVE, PAIR	01220000241893	081110001FOOTTOEPROTEM
EU1412-MBFITGS1	GelSmart® M-Gel ACHILLES/DORSUM PROTECTION SLEEVE, SM-MD	01220000241909	081110001FOOTTOEPROTEM
EU1413-MBFITGS1	GelSmart® M-Gel ACHILLES/DORSUM PROTECTION SLEEVE, LG-XL	01220000241916	081110001FOOTTOEPROTEM
EU3004/05-MNCCS2	NatraCure® M2-Gel GEL METATARSAL PAD WITH TOE LOOP, SMALL, RT AND LF	01220000240537	081110001FOOTTOEPROTEM
EU3006/07-MNCCS2	NatraCure® M2-Gel GEL METATARSAL PAD WITH TOE LOOP, LARGE, RT AND LF	01220000240544	081110001FOOTTOEPROTEM
10021-00CAT-4PK	NatraCure® M-Gel CUSHIONED TOE WRAPS, 4 PCS, ONE SIZE	00811100019751	081110001TOESEPUG
10021-00NCBC2PK	NatraCure® M-Gel CUSHIONED TOE WRAPS, 2 PCS, ONE SIZE	00810001500337	081110001TOESEPUG
10021-00NCBC6PK	NatraCure® M-Gel CUSHIONED TOE WRAPS, 6 PCS, ONE SIZE	00811100019829	081110001TOESEPUG
1105-M RET6PK	NatraCure® M2-Gel ALL GEL TOE SEPARATOR, ONE SIZE, 6/pk	00811100019867	081110001TOESEPUG
1110-M-02AQCAT	NatraCure® M2-Gel GEL TOE STETCHER, SM	00011100017498	081110001TOESEPUG
1126-M NCBC 2PK	NatraCure® M-Gel ALL GEL TOE SPREADERS, 2 PCS, ONE SIZE	00811100018563	081110001TOESEPUG
3035-M RET 4PK	NatraCure® M2-Gel UNIVERSAL TOE CREST, ONE SIZE	00811100019782	081110001TOESEPUG
EU10021-00NCBC2	NatraCure® M-Gel CUSHIONED TOE WRAPS, 2 PCS, ONE SIZE	01220000240124	081110001TOESEPUG
EU1006-MGS2	GelSmart® M-Gel GEL TOE SPREADER W/RIB FAB	01220000240810	081110001TOESEPUG
EU1007-MGS2	GelSmart® M-Gel GEL TOE SPREADER W/RIB FAB	01220000240827	081110001TOESEPUG
EU1030-M-04CTZ2	GelSmart® M2-Gel ADVANCED GEL TOE SPREADER WITH TOE LOOP, LG/XL	01220000240919	081110001TOESEPUG
EU1030-MGS3	GelSmart® M2-Gel ADVANCED GEL TOE SPREADER WITH TOE LOOP, LG/XL	01220000240926	081110001TOESEPUG
EU1031-MGS3	GelSmart® M2-Gel ALL GEL TOE SPREADER WITH LOOP, MD	01220000240933	081110001TOESEPUG
EU1031-MNCCS2	NatraCure® M2-Gel ALL GEL TOE SPREADER WITH LOOP, MD	01220000240452	081110001TOESEPUG
EU1032-MGS3	GelSmart® M2-Gel ALL GEL TOE SPREADER WITH LOOP, LG	01220000240940	081110001TOESEPUG
EU1032-MNCCS2	NatraCure® M2-Gel ALL GEL TOE SPREADER WITH LOOP, LG	01220000240469	081110001TOESEPUG
EU1033-MNCBC2	NatraCure® M2-Gel ALL GEL TOE STRETCHER, 1 PR, ONE SIZE	01220000240025	081110001TOESEPUG
EU1035-M-02CTZ2	GelSmart® M2-Gel ADVANCED GEL TOE SPREADER WITH TOE LOOP, 2 PCS, SM-MD	01220000240957	081110001TOESEPUG
EU1035-MGS3	GelSmart® M2-Gel ADVANCED GEL TOE SPREADER WITH TOE LOOP, SM-MD	01220000240964	081110001TOESEPUG
EU1037-02GR/OR2	GelSmart® M2-Gel CUSTOMIZABLE: UNIVERSAL TOE RELIEF WITH TOE LOOP - FOAM INSERTS, SM, 100 pcs	01220000240971	081110001TOESEPUG
EU1037-M-02CTZ2	GelSmart® M2-Gel CUSTOMIZABLE: UNIVERSAL TOE RELIEF WITH TOE LOOP, 2 PCS, SM	01220000240988	081110001TOESEPUG
EU1037-MGS3	GelSmart® M2-Gel UNIV TOE RELIEF W/LOOPTEK, SM	01220000240995	081110001TOESEPUG
EU1038-03GR/OR2	GelSmart® M2-Gel CUSTOMIZABLE: UNIVERSAL TOE RELIEF WITH TOE LOOP - FOAM INSERTS, MD, 100 PCS	01220000242548	081110001TOESEPUG
EU1038-M-03CTZ2	GelSmart® M2-Gel CUSTOMIZABLE: UNIVERSAL TOE RELIEF WITH TOE LOOP, 2 PCS, MD	01220000241008	081110001TOESEPUG
EU1038-MGS3	GelSmart® M2-Gel UNIVERSAL TOE RELIEF WITH TOE LOOP, MD	01220000241015	081110001TOESEPUG
EU1039-04GR/OR2	GelSmart® M2-Gel CUSTOMIZABLE: UNIVERSAL TOE RELIEF WITH TOE LOOP - FOAM INSERTS, LG, 100 PCS	01220000241022	081110001TOESEPUG
EU1039-M-04CTZ2	GelSmart® M2-Gel CUSTOMIZABLE: UNIVERSAL TOE RELIEF WITH TOE LOOP, 2 PCS, LG	01220000241039	081110001TOESEPUG
EU1039-MGS3	GelSmart® M2-Gel UNIVERSAL TOE RELIEF WITH TOE LOOP, LG	01220000241046	081110001TOESEPUG
EU1040-02GR/OR2	GelSmart® M2-Gel CUSTOMIZABLE: DOUBLE LOOP TOE CORRECTOR - FOAM INSERTS, SM, 100 PCS	01220000241053	081110001TOESEPUG
EU1040-04GR/OR2	GelSmart® M2-Gel CUSTOMIZABLE: DOUBLE LOOP TOE CORRECTOR - FOAM INSERTS, LG, 100 PCS	01220000241060	081110001TOESEPUG

Form Number: FRM F-032-01

EFFECTIVE ONLY ON DATE OF PRINT: 7/15/21

Page 4 of 7

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Declaration of Conformity Certificate

Reference Number	Description	UDI-DI	Basic UDI-DI
EU1040-M-02CTZ2	GelSmart® M2-Gel CUSTOMIZABLE: DOUBLE LOOP TOE CORRECTOR, 2 PCS, SM	01220000241077	081110001TOESEPEG
EU1040-M-02GS3	GelSmart® M2-Gel DOUBLE LOOP TOE CORRECTOR, SM	01220000241084	081110001TOESEPEG
EU1040-M-04CTZ2	GelSmart® M2-Gel CUSTOMIZABLE: DOUBLE LOOP TOE CORRECTOR, 2 PCS, LG	01220000241091	081110001TOESEPEG
EU1040-M-04GS3	GelSmart® M2-Gel DOUBLE LOOP TOE CORRECTOR, LG	01220000241107	081110001TOESEPEG
EU1100-MGS3	GelSmart® M2-Gel GEL TOE SEPERATORS, 3 PCS, SM	01220000241206	081110001TOESEPEG
EU1102-MGS3	GelSmart® M2-Gel GEL TOE SEPERATORS, 3 PCS, LG	01220000241213	081110001TOESEPEG
EU1102-MNCBC2	NatraCure® M2-Gel ALL GEL TOE SEPARATORS, 2 PCS, ONE SIZE	01220000240049	081110001TOESEPEG
EU1103-MGS3	GelSmart® M2-Gel GEL TOE SEPERATORS, 3 PCS, XL	01220000241220	081110001TOESEPEG
EU1104-MGS3	GelSmart® M2-Gel ALL GEL TOE SEPARATOR W/LOOP, SM	01220000241237	081110001TOESEPEG
EU1105-MGS3	GelSmart® M2-Gel ALL GEL TOE SEPARATORS, 3 PCS. MD	01220000241244	081110001TOESEPEG
EU1105-MNCBC2	NatraCure® M2-Gel ALL GEL TOE SEPARATORS, 2 PCS, ONE SIZE	01220000240056	081110001TOESEPEG
EU1106-MGS3	GelSmart® M2-Gel ALL GEL TOE SEPERATORS, 3 PCS, LG	01220000241251	081110001TOESEPEG
EU1110-M02AQGS1	GelSmart® M2-Gel ALL GEL TOE STRETCHER, SM	01220000241268	081110001TOESEPEG
EU1110-M02PKGS1	GelSmart® M2-Gel GEL TOE STRETCHER, SM	01220000241275	081110001TOESEPEG
EU1110-M04AQGS1	GelSmart® M2-Gel GEL TOE STRETCHER, LG	01220000241282	081110001TOESEPEG
EU1110-M04PKGS1	GelSmart® M2-Gel GEL TOE STRETCHER, LG	01220000241299	081110001TOESEPEG
EU1125-MGS3	GelSmart® M-Gel TOE SPREADER, 3 PCS, SM	01220000241305	081110001TOESEPEG
EU1126-MGS3	GelSmart® M-Gel TOE SPREADER, 3 PCS, MD	01220000241312	081110001TOESEPEG
EU1127-MGS3	GelSmart® M-Gel TOE SPREADER, 3 PCS, LG	01220000241329	081110001TOESEPEG
EU1131-UNCBC2	NatraCure® U-Gel DRESS SANDAL SPREADER, ONE SIZE	01220000240070	081110001TOESEPEG
EU1320-M-00GS1	GelSmart® M2-Gel DOUBLE LOOP TAILOR BUNION SPREADER, ONE SIZE	01220000241749	081110001TOESEPEG
EU3020-M-02LGS1	GelSmart® M2-Gel THREE LOOP HAMMERTOE CORRECTOR, SM-MD, LF	01220000241923	081110001TOESEPEG
EU3020-M-02RGS1	GelSmart® M2-Gel THREE LOOP HAMMERTOE CORRECTOR, SM-MD, RT	01220000241930	081110001TOESEPEG
EU3020-M-04LGS1	GelSmart® M2-Gel THREE LOOP HAMMERTOE CORRECTOR, LG-XL, LF	01220000241947	081110001TOESEPEG
EU3020-M-04RGS1	GelSmart® M2-Gel THREE LOOP HAMMERTOE CORRECTOR, LG-XL, RT	01220000241954	081110001TOESEPEG
EU3027-MGS2	GelSmart® M2-Gel TOE CREST, MEDIUM RIGHT	01220000241961	081110001TOESEPEG
EU3028-MGS2	GelSmart® M2-Gel TOE CREST, MEDIUM LEFT	01220000241978	081110001TOESEPEG
EU3029-MGS2	GelSmart® M2-Gel TOE CREST, LARGE RIGHT	01220000241992	081110001TOESEPEG
EU3030-MGS2	GelSmart® M2-Gel TOE CREST, LARGE LEFT	01220000241985	081110001TOESEPEG
EU3035-MGS2	GelSmart® M2-Gel ALL GEL UNIVERSAL TOE CREST, 2 PCS, ONE SIZE	01220000242005	081110001TOESEPEG
EU3035-MNCBC1	NatraCure® M2-Gel ALL GEL UNIVERSAL TOE CREST, ONE SIZE	01220000240100	081110001TOESEPEG
EU3037-M02CTZL2	GelSmart® M2-Gel CUSTOMIZABLE TOE CREST, 2 PCS, SM-MD, LEFT	01220000242012	081110001TOESEPEG
EU3037-M02CTZR2	GelSmart® M2-Gel CUSTOMIZABLE TOE CREST, 2 PCS. SM-MD, RIGHT	01220000242029	081110001TOESEPEG
EU3037-M04CTZL2	GelSmart® M2-Gel CUSTOMIZABLE TOE CREST, 2 PCS, LG-XL, LEFT	01220000242036	081110001TOESEPEG
EU3037-M04CTZR2	GelSmart® M2-Gel CUSTOMIZABLE TOE CREST, 2 PCS, LG-XL, RIGHT	01220000242043	081110001TOESEPEG
EU8102-U3NCCS1	NatraCure® U-Gel FLEXIBLE SLEF ADHESIVE DOTS, ONE SIZE	01220000240667	081110001TOESEPEG
1298-MC CAT	NatraCure® M-Gel DOUBLE BUNION METATARSAL SLEEVE, SM/MD	00811100015982	081110001HALVALL6
1303-MC CAT	NatraCure® M-Gel BUNION RELIEF SLEEVE W/GEL PAD, COVERED, THIN DRESS, SM	00811100016002	081110001HALVALL6
1304-MC CAT	NatraCure® M-Gel BUNION RELIEF SLEEVE W/GEL PAD, COVERED, THIN DRESS, LG	00811100016019	081110001HALVALL6
1315-M RET6PK	NatraCure® M2-Gel ALL GEL BUNION GUARD & TOE SPREADER, 6 PCS, ONE SIZE	00811100019515	081110001HALVALL6
1319-M RET6PK	NatraCure® M2-Gel PINKY TOE BUNION GUARD, 6 PCS, ONE SIZE	00811100019508	081110001HALVALL6
EU1296-MCGS1	GelSmart® M-Gel DOUBLE BUNION METATARSAL SLEEVE, XXL	01220000241527	081110001HALVALL6
EU1298-MCGS1	GelSmart® M-Gel DOUBLE BUNION METATARSAL SLEEVE, SM-MD	01220000241541	081110001HALVALL6
EU1298-MCNC1	NatraCure® M-Gel DOUBLE BUNION METATARSAL SLEEVE, SM-MD	01220000241558	081110001HALVALL6
EU1299-MCGS1	GelSmart® M-Gel DOUBLE BUNION METATARSAL SLEEVE, LG/XL	01220000241565	081110001HALVALL6
EU1299-MCNC1	NatraCure® M-Gel DOUBLE BUNION METATARSAL SLEEVE, LG/XL	01220000241572	081110001HALVALL6
EU1300-SCGS2	GelSmart® S-Gel DRESS BUNION RELIEF SLEEVE WITH GEL METATARSAL PAD, 2 PCS, SM/MD	01220000241589	081110001HALVALL6
EU1301-SCGS2	GelSmart® S-Gel DRESS BUNION RELIEF SLEEVE WITH GEL METATARSAL PAD, 2 PCS, LG/XL	01220000241602	081110001HALVALL6
EU1302-SCGS2	GelSmart® S-Gel DRESS BUNION RELIEF SLEEVE WITH GEL METATARSAL PAD, 2 PCS, XXL	01220000241619	081110001HALVALL6
EU1303-MCNCSS1	NatraCure® M-Gel DRESS BUNION RELIEF PAD, SM	01220000240476	081110001HALVALL6
EU1304-MCNCSS1	NatraCure® M-Gel DRESS BUNION RELIEF PAD, LG	01220000240483	081110001HALVALL6
EU1311-M-02GS1	GelSmart® M-Gel BUNION RELIEF W/APER CUSH, SM-MD	01220000241626	081110001HALVALL6
EU1311-M-04GS1	GelSmart® M-Gel BUNION RELIEF W/APER CUSH, LG-XLG	01220000241633	081110001HALVALL6
EU1311-M02NC1	NatraCure® M-Gel BUNION RELIEF W/APER CUSH, SM-MD	01220000241640	081110001HALVALL6
EU1311-M04NC1	NatraCure® M-Gel BUNION RELIEF W/APER CUSH, LG-XLG	01220000241657	081110001HALVALL6

Declaration of Conformity Certificate

Reference Number	Description	UDI-DI	Basic UDI-DI
EU1315-00GR/OR2	GelSmart® M2-Gel CUSTOMIZABLE: BUNION TOE SPREADER – Foam Inserts, 100 PCS, ONE SIZE	01220000241688	081110001HALVALL6
EU1315-M-00CTZ2	GelSmart® M2-Gel CUSTOMIZABLE: BUNION TOE SPREADER, 2 PCS, ONE SIZE	01220000241695	081110001HALVALL6
EU1315-MGS2	GelSmart® M2-Gel GEL BUNION GUARD AND TOE SPREADER, 2 PCS, ONE SIZE	01220000241701	081110001HALVALL6
EU1315-MNCBC1	NatraCure® M2-Gel GEL BUNION GUARD AND TOE SPREADER, ONE SIZE	01220000240087	081110001HALVALL6
EU1316-MGS2	GelSmart® M2-Gel ALL GEL BIG TOE BUNION GUARD	01220000241718	081110001HALVALL6
EU1316-MNCBC1	NatraCure® M2-Gel BIG TOE BUNION GUARD VALUE PACK	01220000240094	081110001HALVALL6
EU1317-M-00GS1	GelSmart® M2-Gel ALL GEL DOUBLE LOOP BUNION SPREADER, ONE SIZE	01220000241725	081110001HALVALL6
EU1319-MGS1	GelSmart® M2-Gel PINKY TOE BUNION GUARD, ONE SIZE	01220000241732	081110001HALVALL6
EU1319-MNCCS1	NatraCure® M2-Gel PINKY TOE BUNION GUARD, ONE SIZE	01220000240490	081110001HALVALL6
EU8212-UGS3	GelSmart® U-Gel SELF ADHESIVE BUNION BUTTON, ONE SIZE	01220000242418	081110001HALVALL6
10018-02CAT2PK	NatraCure® T-Gel ALL GEL ARCH SLEEVE, 1 PR, SM/MD	00810001500078	081110001FLATSOCK4D
10018-04CAT2PK	NatraCure® T-Gel ALL GEL ARCH SLEEVE, 1 PR, LG/XL	00810001500085	081110001FLATSOCK4D
1283-MC CAT 2PK	NatraCure® M-Gel ARCH FIXER, 1 PR, WM 35-41; MN UP TO 40	00811100016989	081110001FLATSOCK4D
1284-MC CAT 2PK	NatraCure® M-Gel ARCH FIXER, 1 PR, WM 41.5-45.5; MN 41-45	00811100016996	081110001FLATSOCK4D
1290-M-00 CAT	NatraCure® M-Gel ARCH SLEEVE, 1 PR, ONE SIZE	00811100016781	081110001FLATSOCK4D
EU10018-02NC2	NatraCure® T-Gel ALL GEL ARCH SLEEVE, 1 PR, SM/MD	01220000240162	081110001FLATSOCK4D
EU10018-04NC2	NatraCure® T-Gel ALL GEL ARCH SLEEVE, 1 PR, LG/XL	01220000240179	081110001FLATSOCK4D
EU1290-M00NC2	NatraCure® M-Gel ARCH SLEEVES, 1 PR, ONE SIZE	01220000241503	081110001FLATSOCK4D
7000-SC-GS1PRPK	GelSmart® S-Gel 3/4 LENGTH DUAL DUROMETER DEEP INSOLE, COVERED, SM	00811100019324	081110001ORTHINS4L
8120-U NCBC 2PK	NatraCure® U-Gel UGEL FLEXIBLE 3/4 LENGTH DRESS INSOLE	00811100018655	081110001ORTHINS4L
EU5025-SGS1	GelSmart® S-Gel MEDIUM RECOVERY HEEL CUP with soft center spot, SM	01220000242074	081110001ORTHINS4L
EU5026-SGS1	GelSmart® S-Gel MEDIUM RECOVERY HEEL CUP with soft center spot, MD	01220000242081	081110001ORTHINS4L
EU5027-SGS1	GelSmart® S-Gel MEDIUM RECOVERY HEEL CUP with soft center spot, LG	01220000242098	081110001ORTHINS4L
EU5031-SGS1	GelSmart® S-Gel MED. RECOVERY HEEL CUP, XLG	01220000242104	081110001ORTHINS4L
EU5032-SGS1	GelSmart® S-Gel MED. RECOVERY HEEL CUP, XXLG	01220000242111	081110001ORTHINS4L
EU5040-S-01GS1	GelSmart® SILICONE HEEL CUP WITH STAY-PUT TECHNOLOGY, 1 PR, XS	01220000242555	081110001ORTHINS4L
EU5040-S-02GS1	GelSmart® SILICONE HEEL CUPS with stay-put technology, 1 PR, SM/MD	01220000242562	081110001ORTHINS4L
EU5040-S-04GS1	GelSmart® SILICONE HEEL CUPS with stay-put technology, 1 PR, LG/XL	01220000242579	081110001ORTHINS4L
EU5040-S02NC1	NatraCure® S-Gel SILICONE HEEL CUPS with stay-put technology, 1 PR, SM/MD	01220000240773	081110001ORTHINS4L
EU5040-S04NC1	NatraCure® S-Gel SILICONE HEEL CUPS with stay-put technology, 1 PR, LG/XL	01220000240780	081110001ORTHINS4L
EU5050-SGS1	GelSmart® S-Gel MEDIUM RECOVERY HEEL CUP with soft spur spot, 1 PR, SM	01220000242128	081110001ORTHINS4L
EU5051-SGS1	GelSmart® S-Gel MEDIUM RECOVERY HEEL CUP with soft spur spot, 1 PR, MD	01220000242135	081110001ORTHINS4L
EU5052-SGS1	GelSmart® S-Gel MEDIUM RECOVERY HEEL CUP with soft spur spot, 1 PR, LG	01220000242142	081110001ORTHINS4L
EU5056-SGS1	GelSmart® S-Gel MEDIUM RECOVERY HEEL CUP with soft spur spot, 1 PR, XL	01220000242159	081110001ORTHINS4L
EU5057-SGS1	GelSmart® S-Gel MEDIUM RECOVERY HEEL CUP with soft spur spot, 1 PR, XXL	01220000242166	081110001ORTHINS4L
EU5075-SCNCCS1	NatraCure® S-Gel S-GEL POSTED HEEL WEDGE WITH SOFT SPUR SPOT, 1 PR, SM	01220000240568	081110001ORTHINS4L
EU5076-SCNCCS1	NatraCure® S-Gel S-GEL POSTED HEEL WEDGE WITH SOFT SPUR SPOT, 1 PR, MD	01220000240575	081110001ORTHINS4L
EU5077-SCNCCS1	NatraCure® S-Gel S-GEL POSTED HEEL WEDGE WITH SOFT SPUR SPOT, 1 PR, LG	01220000240582	081110001ORTHINS4L
EU5125-SCNCCS1	NatraCure® S-Gel HEEL WEDGE (TRADITIONAL DESIGN) WITH REMOVABLE SPUR, 1 PR, SM	01220000240599	081110001ORTHINS4L
EU5125-SGS1	GelSmart® S-Gel HEEL W/REMOVABLE SPUR PLUG, SM	01220000242173	081110001ORTHINS4L
EU5126-SCNCCS1	NatraCure® S-Gel HEEL WEDGE (TRADITIONAL DESIGN) WITH REMOVABLE SPUR, 1 PR, MD	01220000240605	081110001ORTHINS4L
EU5126-SGS1	GelSmart® S-Gel HEEL W/REMOVABLE SPUR PLUG, MD	01220000242180	081110001ORTHINS4L
EU5127-SCNCCS1	NatraCure® S-Gel HEEL WEDGE (TRADITIONAL DESIGN) WITH REMOVABLE SPUR, 1 PR, LG	01220000240612	081110001ORTHINS4L
EU5127-SGS1	GelSmart® S-Gel HEEL W/REMOVABLE SPUR PLUG, LG	01220000242197	081110001ORTHINS4L
EU7000-SGS1	GelSmart® S-Gel DUAL DURO DEEP 3/4 INSOLE, SM	01220000242234	081110001ORTHINS4L
EU7001-SGS1	GelSmart® S-Gel DUAL DURO DEEP 3/4 INSOLE, MD	01220000242241	081110001ORTHINS4L
EU7002-SGS1	GelSmart® S-Gel DUAL DURO DEEP 3/4 INSOLE, LG	01220000242258	081110001ORTHINS4L
EU7003-SGS1	GelSmart® S-Gel DUAL DURO DEEP 3/4 INSOLE, XL	01220000242272	081110001ORTHINS4L
EU7004-SGS1	GelSmart® S-Gel DUAL DURO DEEP 3/4 INSOLE, XXL	01220000242289	081110001ORTHINS4L
EU7025-SCNCCS1	NatraCure® S-Gel 3/4 THIN INSOLE, SM	01220000240629	081110001ORTHINS4L
EU7026-SCNCCS1	NatraCure® S-Gel 3/4 THIN INSOLE, MD	01220000240636	081110001ORTHINS4L
EU7027-SCNCCS1	NatraCure® S-Gel 3/4 THIN INSOLE, LG	01220000240643	081110001ORTHINS4L
EU7050-SGS1	GelSmart® S-Gel DD INSOLE + SOFT RELIEF, SM	01220000242265	081110001ORTHINS4L
EU7051-SGS1	GelSmart® S-Gel DD INSOLE + SOFT RELIEF, MD	01220000242296	081110001ORTHINS4L
EU7052-SGS1	GelSmart® S-Gel DD INSOLE + SOFT RELIEF, LG	01220000242302	081110001ORTHINS4L
EU7053-SGS1	GelSmart® S-Gel DD INSOLE + SOFT RELIEF, XL	01220000242319	081110001ORTHINS4L

Form Number: FRM F-032-01

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Page 6 of 7

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Declaration of Conformity Certificate

Reference Number	Description	UDI-DI	Basic UDI-DI
EU7054-SGS1	GelSmart® S-Gel DD INSOLE + SOFT RELIEF, XXL	01220000242326	081110001ORTHINS4L
EU7055-SGS1	GelSmart® S-Gel DD INSOLE + SOFT RELIEF, XXXL	01220000242333	081110001ORTHINS4L
EU8101-UGS1	GelSmart® U-Gel FLEXIBLE SELF ADHESIVE HEEL GRIP, ONE SIZE	01220000242395	081110001ORTHINS4L
EU8101-UNCCS1	NatraCure® U-Gel FLEXIBLE SELF ADHESIVE HEEL GRIP, ONE SIZE	01220000240650	081110001ORTHINS4L
EU8110-UNCBC2	NatraCure® U-Gel FLEXIBLE BALL OF FOOT CUSHION, ONE SIZE	01220000240117	081110001ORTHINS4L
EU8111-UGS1	GelSmart® U-Gel FLEXIBLE HEEL CUSHION, ONE SIZE	01220000242401	081110001ORTHINS4L
EU8120-UNCBC2	NatraCure® U-Gel 3/4 LENGTH PU DRESS INSOLE, ONE SIZE	01220000240148	081110001ORTHINS4L