

**DECLARATION OF CONFORMITY**

1) Manufacturer (Name, department): **Brownmed, Inc**

Address: **1300 Lundberg Drive West, Spirit Lake, IA 51360**

and

2) European authorized representative: **CEpartner4U BV,**

Address: **ESDOORNLAAN 13, 3951DB MAARN, THE NETHERLANDS;**

(on product labels printed as:

CEpartner4U , ESDOORNLAAN 13, 3951DB MAARN, THE NETHERLANDS www.cepartner4u.eu)

3) Product(s) (name, type or model/batch number, etc.):

**Lower Extremity, Upper Extremity, Wound Care, Ice therapy Products, Splints,  
Shoe Inserts, Foot Neuropathy System**  
*see appendix*

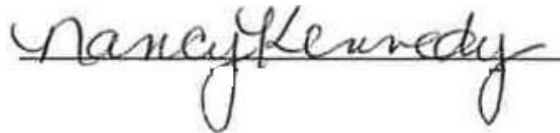
4) The product(s) described above is in conformity with:

<u>Title</u>	<u>Document No.</u>
<b>Medical Device Directive</b>	93/42/EEC

5) Additional information (conformity procedure, Notified Body, CE certificate, etc.):

Conformity assessment procedure for CE marking: Medical Device Directive, Annex VII

Boston, USA 2020-06-10



Nancy Kennedy, Director International Sales

(Place & date of issue (yyyy-mm-dd))

(name; function and signature of manufacturer)

Date: 2020-06-10

List of devices.

Device name	Make	Model	Risk class / rule <sup>1</sup>	P/N	First date of CE-Compliance
Group: Lower Extremity					
STEADY STEP®	SHIN SLEEVE™	Small - Black	Class I/rule1	51054	2003-01-20
STEADY STEP®	SHIN SLEEVE™	Medium - Black	Class I/rule1	51055	2003-01-20
STEADY STEP®	SHIN SLEEVE™	Large - Black	Class I/rule1	51056	2003-01-20
STEADY STEP®	SHIN SLEEVE™	X-Large - Black	Class I/rule1	51057	2003-01-20
STEADY STEP®	HEEL HUGGER™	Small w/Gel	Class I/rule1	50071	2003-01-20
STEADY STEP®	HEEL HUGGER™	Medium w/Gel	Class I/rule1	50072	2003-01-20
STEADY STEP®	HEEL HUGGER™	Large w/Gel	Class I/rule1	50073	2003-01-20
STEADY STEP®	HEEL HUGGER™	X-Large w/Gel	Class I/rule1	50074	2003-01-20
STEADY STEP®	HEEL HUGGER™ with Magnets	Small-Gel & Magnets	Class I/rule1	50161	2003-01-20
STEADY STEP®	HEEL HUGGER™ with Magnets	Medium-Gel & Magnets	Class I/rule1	50162	2003-01-20
STEADY STEP®	HEEL HUGGER™ with Magnets	Large-Gel & Magnets	Class I/rule1	50163	2003-01-20
STEADY STEP®	HEEL HUGGER™ with Magnets	X-Large-Gel & Magnets	Class I/rule1	50164	2003-01-20
STEADY STEP®	PERFORM 8™	Small Universal	Class I/rule1	50051	2003-01-20
STEADY STEP®	PERFORM 8™	Medium Universal	Class I/rule1	50052	2003-01-20
STEADY STEP®	PERFORM 8™	Large Universal	Class I/rule1	50053	2003-01-20
STEADY STEP®	PERFORM 8™	X-Large Universal	Class I/rule1	50054	2003-01-20
STEADY STEP®	TOE HOLD®	Small/Medium Right	Class I/rule1	50201	2003-01-20
STEADY STEP®	TOE HOLD®	Small/Medium Left	Class I/rule1	50202	2003-01-20
STEADY STEP®	TOE HOLD®	Medium/Large Right	Class I/rule1	50203	2003-01-20
STEADY STEP®	TOE HOLD®	Medium/Large Left	Class I/rule1	50204	2003-01-20
STEADY STEP®	Sol Step™	Small	Class I/rule1	50040	2005-01-21
STEADY STEP®	Sol Step™	Medium	Class I/rule1	50041	2005-01-21
STEADY STEP®	Sol Step™	Large	Class I/rule1	50042	2005-01-21
STEADY STEP®	Sol Step™	XLarge	Class I/rule1	50043	2005-01-21
STEADY STEP®	Satin Heels®	Universal in Box 2/pkg	Class I/rule1	50140	2011-12-05
STEADY STEP®	Satin Heels®	Universal in Bag 2/pkg	Class I/rule1	50145	2011-12-05
STEADY STEP®	STEADY STEP® WALKER	Small	Class I/rule1	52021	2003-01-20
STEADY STEP®	STEADY STEP® WALKER	Medium	Class I/rule1	52022	2003-01-20

<sup>1</sup> See risk classification in Medical Device Directive, annex IX

Device name	Make	Model	Risk class / rule <sup>1</sup>	P/N	First date of CE-Compliance
STEADY STEP®	STEADY STEP® WALKER	Large	Class I/rule1	52023	2003-01-20
STEADY STEP®	STEADY STEP® WALKER	LOW TOP Small	Class I/rule1	52031	2003-01-20
STEADY STEP®	STEADY STEP® WALKER	LOW TOP Medium	Class I/rule1	52032	2003-01-20
STEADY STEP®	STEADY STEP® WALKER	LOW TOP Large	Class I/rule1	52033	2003-01-20
STEADY STEP®	HERBST CRADLE™	Small	Class I/rule1	04020	2003-01-20
STEADY STEP®	HERBST CRADLE™	Medium	Class I/rule1	04021	2003-01-20
STEADY STEP®	HERBST CRADLE™	Large	Class I/rule1	04022	2003-01-20
IMAK®	Arthritis Socks	Small	Class I/rule1	A20190	2012-01-03
IMAK®	Arthritis Socks	Medium	Class I/rule1	A20191	2012-01-03
IMAK®	Arthritis Socks	Large	Class I/rule1	A20192	2012-01-03
IMAK®	Plantar Fasciitis Night Splint	Universal	Class I/rule1	A50320	2011-05-17
NICE STRETCH®	X Lite	Universal	Class I/rule1	50320	2008-11
NICE STRETCH®	90	Small	Class I/rule1	50310	2008-11
NICE STRETCH®	90	Medium	Class I/rule1	50311	2008-11
NICE STRETCH®	90	Large	Class I/rule1	50312	2008-11
NICE STRETCH®	Original	Small	Class I/rule1	51000	2003-01-20
NICE STRETCH®	Original	Medium	Class I/rule1	51001	2003-01-20
NICE STRETCH®	Original	Large	Class I/rule1	51002	2003-01-20
NICE STRETCH®	Original	X-Large	Class I/rule1	51003	2003-01-20
NICE STRETCH®	Original	Small w/o ice	Class I/rule1	51010	2003-01-20
NICE STRETCH®	Original	Medium w/o ice	Class I/rule1	51004	2003-01-20
NICE STRETCH®	Original	Large w/o ice	Class I/rule1	51005	2003-01-20
NICE STRETCH®	Original	X-Large w/o ice	Class I/rule1	51006	2003-01-20
NICE STRETCH®	PF Sleeve	Small/Medium	Class I/rule1	53100	2018-12-11
NICE STRETCH®	PF Sleeve	Large/X-Large	Class I/rule1	53101	2018-12-11
NICE STRETCH®	PF Kit	Small/Medium	Class I/rule1	53104	2018-12-11
NICE STRETCH®	PF Kit	Large/X-Large	Class I/rule1	53105	2018-12-11
NICE STRETCH®	Replacement Ice Packs	Small/Medium	Class I/rule1	51007	2003-01-20
NICE STRETCH®	Replacement Ice Packs	Medium/Large	Class I/rule1	51008	2003-01-20
NICE STRETCH®	X	Small in bag	Class I/rule1	51020	2006-11-22
NICE STRETCH®	X	Medium in bag	Class I/rule1	51021	2006-11-22
NICE STRETCH®	X	Large in bag	Class I/rule1	51022	2006-11-22
NICE STRETCH®	X	X-Large in bag	Class I/rule1	51023	2006-11-22
NICE STRETCH®	X	Small w/ Retail Box	Class I/rule1	51030	2006-11-22
NICE STRETCH®	X	Medium w/ Retail Box	Class I/rule1	51031	2006-11-22
NICE STRETCH®	X	Large w/ Retail Box	Class I/rule1	51032	2006-11-22
NICE STRETCH®	X	X-Large w/ Retail Box	Class I/rule1	51033	2006-11-22
NICE STRETCH®	DORSAL	S/M	Class I/rule1	52060	2006-11-22
NICE STRETCH®	DORSAL	L/XL	Class I/rule1	52061	2006-11-22
Spark®	Kinetic Knee Sleeve	Small	Class I/rule1	40410	2019-07-17
Spark®	Kinetic Knee Sleeve	Medium	Class I/rule1	40411	2019-07-17
Spark®	Kinetic Knee Sleeve	Large	Class I/rule1	40412	2019-07-17
Spark®	Kinetic Calf Sleeve	Small	Class I/rule1	40420	2019-07-17
Spark®	Kinetic Calf Sleeve	Medium	Class I/rule1	40421	2019-07-17
Spark®	Kinetic Calf Sleeve	Large	Class I/rule1	40422	2019-07-17
Spark®	Kinetic Ankle Sleeve	Small	Class I/rule1	40426	2019-07-17
Spark®	Kinetic Ankle Sleeve	Medium	Class I/rule1	40427	2019-07-17
Spark®	Kinetic Ankle Sleeve	Large	Class I/rule1	40428	2019-07-17

Device name	Make	Model	Risk class / rule <sup>1</sup>	P/N	First date of CE-Compliance
Group: Upper Extremity			Class I/rule1		
IMAK®	Pil-O-Splint	Universal	Class I/rule1	A10312	2010-04-01
IMAK®	Pil-O-Splint	Adjustable	Class I/rule1	A10112	2010-04-01
IMAK®	Flex8™ Elbow Brace	Small	Class I/rule1	61001	2011-12-05
IMAK®	Flex8™ Elbow Brace	Medium	Class I/rule1	61002	2011-12-05
IMAK®	Flex8™ Elbow Brace	Large	Class I/rule1	61003	2011-12-05
IMAK®	Flex8™ Elbow Brace	X-Large	Class I/rule1	61004	2011-12-05
IMAK®	WRISTIMER®	Small - To 6.5"	Class I/rule1	60000	2003-01-20
IMAK®	WRISTIMER®	Medium - 6.5"-7.5"	Class I/rule1	60010	2003-01-20
IMAK®	WRISTIMER®	Large - Over 7.5"	Class I/rule1	60020	2003-01-20
IMAK®	WRISTIMER PM®	Universal	Class I/rule1	60500	2003-01-20
IMAK®	Elbow Band	Universal	Class I/rule1	A10301	2010-04-01
IMAK®	Elbow Support	Universal	Class I/rule1	A10113	2010-04-01
IMAK®	Elbow Support	X-Large	Class I/rule1	A10110	2010-04-01
IMAK®	Elbow Support PM	Universal	Class I/rule1	A10172	2010-04-01
IMAK®	Arthritis Elbow Sleeve	Small	Class I/rule1	A20155	2018-12-11
IMAK®	Arthritis Elbow Sleeve	Medium	Class I/rule1	A20156	2018-12-11
IMAK®	Arthritis Elbow Sleeve	Large	Class I/rule1	A20157	2018-12-11
IMAK®	Arthritis Glove	X- Small	Class I/rule1	A20173	2013-12-04
IMAK®	Arthritis Glove	Small	Class I/rule1	A20170	2010-04-01
IMAK®	Arthritis Glove	Medium	Class I/rule1	A20171	2010-04-01
IMAK®	Arthritis Glove	Large	Class I/rule1	A20172	2010-04-01
IMAK®	Arthritis Glove	X-Large	Class I/rule1	A20174	2013-12-04
IMAK®	Arthritis Thumb	Small	Class I/rule1	A20178	2018-12-11
IMAK®	Arthritis Thumb	Medium	Class I/rule1	A20179	2018-12-11
IMAK®	Arthritis Thumb	Large	Class I/rule1	A20180	2018-12-11
IMAK®	Arthritis Wrist	Small	Class I/rule1	A20130	2018-12-11
IMAK®	Arthritis Wrist	Medium	Class I/rule1	A20131	2018-12-11
IMAK®	Arthritis Wrist	Large	Class I/rule1	A20132	2018-12-11
IMAK®	Active Glove	Small	Class I/rule1	A20185	2012-01-03
IMAK®	Active Glove	Medium	Class I/rule1	A20186	2012-01-03
IMAK®	Active Glove	Large	Class I/rule1	A20187	2012-01-03
IMAK®	Smart Glove	X-Small	Class I/rule1	A20111	2010-04-01
IMAK®	Smart Glove	Small	Class I/rule1	A20125	2010-04-01
IMAK®	Smart Glove	Medium	Class I/rule1	A20126	2010-04-01
IMAK®	Smart Glove	Large	Class I/rule1	A20127	2010-04-01
IMAK®	Smart Glove w/ Thumb	Small	Class I/rule1	A20161	2010-04-01
IMAK®	Smart Glove w/ Thumb	Medium	Class I/rule1	A20162	2010-04-01
IMAK®	Smart Glove w/ Thumb	Large	Class I/rule1	A20163	2010-04-01
IMAK®	Smart Glove PM	Universal`	Class I/rule1	A10111	2010-04-01
IMAK®	Smart Thumb	Small	Class I/rule1	A20178	2010-04-01
IMAK®	Smart Thumb	Medium	Class I/rule1	A20179	2010-04-01
IMAK®	Smart Thumb	Large	Class I/rule1	A20180	2010-04-01
IMAK®	Wrist Wrap	Universal	Class I/rule1	A10302	2010-04-01
IMAK®	Computer Glove	Universal	Class I/rule1	A20128	2010-04-01
IMAK®	Stress Balls	Blue	Class I/rule1	A10129	2011-05-17
IMAK®	Stress Balls	Black	Class I/rule1	A10130	2011-05-17
IMAK®	Stress Balls	Heather Gray	Class I/rule1	A10156	2011-05-17
IMAK®	Neck Support	Universal w/ Gel	Class I/rule1	A30124	2010-04-01
IMAK®	Pain Relief Mask	Universal Retail Box	Class I/rule1	A30131	2010-04-01
IMAK®	Pain Relief Mask	Universal Retail Bag	Class I/rule1	A30135	2010-04-01
IMAK®	Knee Strap	Universal	Class I/rule1	A30137	2010-04-01
IMAK®	Back Cushion	Universal	Class I/rule1	A30122	2010-04-01

Device name	Make	Model	Risk class / rule <sup>1</sup>	P/N	First date of CE-Compliance
IMAK®	HappiNeck Beige	Universal	Class I/rule1	A30111	2010-04-01
IMAK®	HappiNeck - Blue	Universal	Class I/rule1	A30112	2010-04-01
IMAK®	Arm Sling	Universal	Class I/rule1	A30140	2011-12-05
IMAK®	Arm Sling Immobilizer	Universal	Class I/rule1	A30141	2012-12-05
IMAK®	Finger Sleeve	Small	Class I/rule1	A10303	2011-12-22
IMAK®	Finger Sleeve	Medium	Class I/rule1	A10304	2011-12-22
IMAK®	Finger Sleeve	Large	Class I/rule1	A10305	2011-12-22
Spark®	Kinetic Elbow Sleeve	Small	Class I/rule1	40416	2019-07-17
Spark®	Kinetic Elbow Sleeve	Medium	Class I/rule1	40417	2019-07-17
Spark®	Kinetic Elbow Sleeve	Large	Class I/rule1	40418	2019-07-17
Joslin®	Ultimate Armsling	Toddler/SM Child	Class I/rule1	J50001	2019-07-17
Joslin®	Ultimate Armsling	Child/Small Adult	Class I/rule1	J50101	2019-07-17
Joslin®	Ultimate Armsling	Average Adult	Class I/rule1	J50201	2019-07-17
Joslin®	Ultimate Armsling	PRO-3XL	Class I/rule1	J50301	2019-07-17
Joslin®	Ultimate Armsling	Goliath	Class I/rule1	J50401	2019-07-17
Joslin®	ER Sling	Child	Class I/rule1	J61545	2019-07-17
Joslin®	ER Sling	Adult	Class I/rule1	J62545	2019-07-17
Joslin®	ER Sling	Triple X	Class I/rule1	J63545	2019-07-17
Joslin®	Swathe	Child	Class I/rule1	J50601	2019-07-17
Joslin®	Swathe	Adult	Class I/rule1	J50501	2019-07-17
Joslin®	Swathe	Goliath	Class I/rule1	J50701	2019-07-17
Joslin®	Combo	Adult Regular	Class I/rule1	J00711	2019-07-17
Joslin®	Combo	Adult Large	Class I/rule1	J00712	2019-07-17
<b>Group:</b>					
<b>WOUND CARE</b>					
SEAL-TIGHT®	SEAL-TIGHT® Sport-Pediatric (2-10 Years)	Leg	Class I/rule1	20362	2003-01-20
SEAL-TIGHT®	SEAL-TIGHT® Sport Pediatric (2-10 Years)	Arm	Class I/rule1	20363	2003-01-20
SEAL-TIGHT®	SEAL-TIGHT® Sport -Adult	Short Arm	Class I/rule1	20320	2003-01-20
SEAL-TIGHT®	SEAL-TIGHT® Sport -Adult	Long Arm	Class I/rule1	20321	2003-01-20
SEAL-TIGHT®	SEAL-TIGHT® Sport -Adult	Short Leg	Class I/rule1	20322	2003-01-20
SEAL-TIGHT®	SEAL-TIGHT® Sport -Adult	Long Leg	Class I/rule1	20323	2003-01-20
SEAL-TIGHT®	SEAL-TIGHT® Protector- Knee	Small	Class I/rule1	20324	2003-01-20
SEAL-TIGHT®	SEAL-TIGHT® Protector- Knee	Medium	Class I/rule1	20325	2003-01-20
SEAL-TIGHT®	SEAL-TIGHT® Protector- Knee	Large	Class I/rule1	20326	2003-01-20
SEAL-TIGHT®	SEAL-TIGHT® Protector	Small	Class I/rule1	20318	2005-01-21
SEAL-TIGHT®	SEAL-TIGHT® Protector	Medium	Class I/rule1	20317	2005-01-21
SEAL-TIGHT®	SEAL-TIGHT® Protector	Large	Class I/rule1	20319	2005-01-21
SEAL-TIGHT®	SEAL-TIGHT® Original CAST PROTECTORS	Adult Hand	Class I/rule1	20100	2003-01-20
SEAL-TIGHT®	SEAL-TIGHT® Original CAST PROTECTORS	Adult Short Arm	Class I/rule1	20101	2003-01-20
SEAL-TIGHT®	SEAL-TIGHT® Original CAST PROTECTORS	Adult Long Arm	Class I/rule1	20102	2003-01-20

Device name	Make	Model	Risk class / rule <sup>1</sup>	P/N	First date of CE-Compliance
SEAL-TIGHT®	SEAL-TIGHT® Original CAST PROTECTORS	Adult Short Leg	Class I/rule1	20103	2003-01-20
SEAL-TIGHT®	SEAL-TIGHT® Original CAST PROTECTORS	Adult Long Leg	Class I/rule1	20104	2003-01-20
SEAL-TIGHT®	SEAL-TIGHT® Original CAST PROTECTORS	Foot/Ankle	Class I/rule1	20105	2003-01-20
SEAL-TIGHT®	SEAL-TIGHT® Original CAST PROTECTORS	Adult Short Leg Wide	Class I/rule1	20106	2003-01-20
SEAL-TIGHT®	SEAL-TIGHT® Original CAST PROTECTORS	Adult Short Arm Wide	Class I/rule1	20107	2003-01-20
SEAL-TIGHT®	SEAL-TIGHT® Original CAST PROTECTORS	Pediatric Small Arm	Class I/rule1	20200	2003-01-20
SEAL-TIGHT®	SEAL-TIGHT® Original CAST PROTECTORS	Pediatric Medium Arm	Class I/rule1	20201	2003-01-20
SEAL-TIGHT®	SEAL-TIGHT® Original CAST PROTECTORS	Pediatric Large Arm	Class I/rule1	20202	2003-01-20
SEAL-TIGHT®	SEAL-TIGHT® Original CAST PROTECTORS	Pediatric Small Leg	Class I/rule1	20203	2003-01-20
SEAL-TIGHT®	SEAL-TIGHT® Original CAST PROTECTORS	Pediatric Medium Leg	Class I/rule1	20204	2003-01-20
SEAL-TIGHT®	SEAL-TIGHT® Original CAST PROTECTORS	Pediatric Large Leg	Class I/rule1	20205	2003-01-20
SEAL-TIGHT®	SEAL-TIGHT® Original CAST PROTECTORS	16 Piece Pre-pack	Class I/rule1	20302	2003-01-20
SEAL-TIGHT®	SEAL-TIGHT® Shield	5" x 8"	Class I/rule1	20435	2005-01-21
SEAL-TIGHT®	SEAL-TIGHT® Freedom	Adult Arm	Class I/rule1	26500	2011-12-05
SEAL-TIGHT®	SEAL-TIGHT® Freedom	Adult Leg	Class I/rule1	26501	2011-12-05
SEAL-TIGHT®	SEAL-TIGHT® Freedom	Pediatric Arm	Class I/rule1	26502	2011-12-05
SEAL-TIGHT®	SEAL-TIGHT® Freedom	Pediatric Leg	Class I/rule1	26503	2011-12-05
SEAL-TIGHT®	SEAL-TIGHT® Freedom	Universal	Class I/rule1	28002	2011-12-05
SEAL-TIGHT®	SEAL-TIGHT® Seal Band	Arm	Class I/rule1	28075	2011-12-05
SEAL-TIGHT®	SEAL-TIGHT® Seal Band	Leg	Class I/rule1	28076	2011-12-05
<b>Group: ICE THERAPY PRODUCTS</b>			Class I/rule1		
SEALED ICE®	Shin Ice™	Small	Class I/rule1	30011	2005-10-04
SEALED ICE®	Shin Ice™	Medium	Class I/rule1	30012	2005-10-04
SEALED ICE®	Shin Ice™	Large	Class I/rule1	30013	2005-10-04
SEALED ICE®	Shin Ice™	X-Large	Class I/rule1	30014	2005-10-04
SEALED ICE®	Polar Ice™	Shoulder/Hip Wrap	Class I/rule1	30100	2005-10-04

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SEALED ICE®	Polar Ice™	Wrist/Elbow Wrap	Class I/rule1	30101	2005-10-04
SEALED ICE®	Polar Ice™	CPM Knee Wrap	Class I/rule1	30102	2005-10-04
SEALED ICE®	Polar Ice™	Arthroscopy Knee Wrap – Standard	Class I/rule1	30103	2005-10-04
SEALED ICE®	Polar Ice™	Arthroscopy Knee Wrap – Large	Class I/rule1	30104	2005-10-04
SEALED ICE®	Polar Ice™	Foot/Ankle Wrap	Class I/rule1	30105	2005-10-04
SEALED ICE®	Polar Ice™	Quick Wrap	Class I/rule1	30107	2005-10-04
SEALED ICE®	Polar Ice™	Back Wrap	Class I/rule1	30108	2005-10-04
SEALED ICE®	Polar Ice™	TMJ Wrap	Class I/rule1	30109	2005-10-04
SEALED ICE®	Replacement Ice Packs	SEALED ICE® Pack - Shoulder/Hip Wrap	Class I/rule1	31000	2005-10-04
SEALED ICE®	Replacement Ice Packs	SEALED ICE® Pack - Wrist/Elbow Wrap	Class I/rule1	31001	2005-10-04
SEALED ICE®	Replacement Ice Packs	SEALED ICE® Pack - CPM Knee Wrap	Class I/rule1	31002	2005-10-04
SEALED ICE®	Replacement Ice Packs	SEALED ICE® Pack - Arthroscopy Knee Wrap – Standard	Class I/rule1	31003	2005-10-04
SEALED ICE®	Replacement Ice Packs	SEALED ICE® Pack - Arthroscopy Knee Wrap – Large	Class I/rule1	31004	2005-10-04
SEALED ICE®	Replacement Ice Packs	SEALED ICE® Pack - Foot/Ankle Wrap	Class I/rule1	31005	2005-10-04
SEALED ICE®	Replacement Ice Packs	SEALED ICE® Pack - Quick Wrap	Class I/rule1	31007	2005-10-04
SEALED ICE®	Replacement Ice Packs	SEALED ICE® Pack - Back Wrap	Class I/rule1	31008	2005-10-04
SEALED ICE®	Replacement Ice Packs	SEALED ICE® Pack - TMJ Wrap	Class I/rule1	31009	2005-10-04
<b>Group: SPLINTS</b>			Class I/rule1		
PLASTALUME®	PLASTALUME® KITS	Number 27 Digital Kit - 3 each, A-1 thru AB-8	Class I/rule1	10008	2003-01-20
PLASTALUME®	PLASTALUME® KITS	Number 40 Digital Kit - 3 each, plus 13 most popular sizes A-1 thru AB-8	Class I/rule1	10003	2003-01-20
PLASTALUME®	PLASTALUME® KITS	Number 54 Digital Kit - 6 each, A-1 thru AB-8	Class I/rule1	10004	2003-01-20
PLASTALUME®	PLASTALUME® KITS	Number 45 Specialty Kit	Class I/rule1	10030	2003-01-20
PLASTALUME®	PLASTALUME® KITS	Number 30 Stax-Mallet Kit	Class I/rule1	10020	2003-01-20
PLASTALUME®	FINGER SPLINTS-BASEBALLS	Small Blue Foam	Class I/rule1	11111	2003-01-20



Device name	Make	Model	Risk class / rule <sup>1</sup>	P/N	First date of CE-Compliance
PLASTALUME®	FINGER SPLINTS-BASEBALLS	Medium Blue Foam	Class I/rule1	11121	2003-01-20
PLASTALUME®	FINGER SPLINTS-BASEBALLS	Large Blue Foam	Class I/rule1	11131	2003-01-20
PLASTALUME®	FINGER SPLINTS-COTS	X Small Blue Foam	Class I/rule1	10901	2003-01-20
PLASTALUME®	FINGER SPLINTS-COTS	Small Blue Foam	Class I/rule1	10911	2003-01-20
PLASTALUME®	FINGER SPLINTS-COTS	Medium Blue Foam	Class I/rule1	10921	2003-01-20
PLASTALUME®	FINGER SPLINTS-COTS	Large Blue Foam	Class I/rule1	10931	2003-01-20
PLASTALUME®	FINGER SPLINTS-FROGS	Small Blue Foam	Class I/rule1	10801	2003-01-20
PLASTALUME®	FINGER SPLINTS-FROGS	Medium Blue Foam	Class I/rule1	10811	2003-01-20
PLASTALUME®	FINGER SPLINTS-FROGS	Large Blue Foam	Class I/rule1	10821	2003-01-20
PLASTALUME®	FINGER SPLINTS-PROTECTORS	Small Blue Foam	Class I/rule1	10501	2003-01-20
PLASTALUME®	FINGER SPLINTS-PROTECTORS	Medium Blue Foam	Class I/rule1	10511	2003-01-20
PLASTALUME®	FINGER SPLINTS-PROTECTORS	Large Blue Foam	Class I/rule1	10521	2003-01-20
PLASTALUME®	FINGER SPLINTS-SPOONS	Small Blue Foam	Class I/rule1	11011	2003-01-20
PLASTALUME®	FINGER SPLINTS-SPOONS	Medium Blue Foam	Class I/rule1	11021	2003-01-20
PLASTALUME®	FINGER SPLINTS-SPOONS	Large Blue Foam	Class I/rule1	11031	2003-01-20
PLASTALUME®	FINGER SPLINTS-STAX-MALLETS	Stax 1 Flesh	Class I/rule1	10701	2003-01-20
PLASTALUME®	FINGER SPLINTS-STAX-MALLETS	Stax 2 Flesh	Class I/rule1	10702	2003-01-20
PLASTALUME®	FINGER SPLINTS-STAX-MALLETS	Stax 3 Flesh	Class I/rule1	10703	2003-01-20
PLASTALUME®	FINGER SPLINTS-STAX-MALLETS	Stax 4 Flesh	Class I/rule1	10704	2003-01-20
PLASTALUME®	FINGER SPLINTS-STAX-MALLETS	Stax 5 Flesh	Class I/rule1	10705	2003-01-20
PLASTALUME®	FINGER SPLINTS-STAX-MALLETS	Stax 5.5 Flesh	Class I/rule1	10706	2003-01-20
PLASTALUME®	FINGER SPLINTS-STAX-MALLETS	Stax 6 Flesh	Class I/rule1	10707	2003-01-20
PLASTALUME®	FINGER SPLINTS-STAX-MALLETS	Stax 7 Flesh	Class I/rule1	10708	2003-01-20
PLASTALUME®	FINGER SPLINTS-STAX-MALLETS	Stax 1 Clear	Class I/rule1	10730	2011-12-05
PLASTALUME®	FINGER SPLINTS-STAX-MALLETS	Stax 2 Clear	Class I/rule1	10731	2011-12-05
PLASTALUME®	FINGER SPLINTS-STAX-MALLETS	Stax 3 Clear	Class I/rule1	10732	2011-12-05
PLASTALUME®	FINGER SPLINTS-STAX-MALLETS	Stax 4 Clear	Class I/rule1	10733	2011-12-05
PLASTALUME®	FINGER SPLINTS-STAX-MALLETS	Stax 5 Clear	Class I/rule1	10734	2011-12-05
PLASTALUME®	FINGER SPLINTS-STAX-MALLETS	Stax 5.5 Clear	Class I/rule1	10735	2011-12-05



Device name	Make	Model	Risk class / rule <sup>1</sup>	P/N	First date of CE-Compliance
PLASTALUME®	FINGER SPLINTS-STAX-MALLETS	Stax 6 Clear	Class I/rule1	10736	2011-12-05
PLASTALUME®	FINGER SPLINTS-STAX-MALLETS	Stax 7 Clear	Class I/rule1	10737	2011-12-05
PLASTALUME®	STRIPS	1/2" x 18" Blue Foam	Class I/rule1	10601	2003-01-20
PLASTALUME®	STRIPS	1/2" x 18" White Foam	Class I/rule1	10602	2003-01-20
PLASTALUME®	STRIPS	3/4" x 18" Blue Foam	Class I/rule1	10611	2003-01-20
PLASTALUME®	STRIPS	3/4" x 18" White Foam	Class I/rule1	10612	2003-01-20
PLASTALUME®	STRIPS	1" x 18" Blue Foam	Class I/rule1	10621	2003-01-20
PLASTALUME®	STRIPS	1" x 18" White Foam	Class I/rule1	10622	2003-01-20
PLASTALUME®	STRIPS	1.18" X 18" Blue Foam	Class I/rule1	10623	2003-01-20
PLASTALUME®	STRIPS	1.18" x 18" White Foam	Class I/rule1	10624	2003-01-20
PLASTALUME®	STRIPS	1.57" x 18" Blue Foam	Class I/rule1	10625	2003-01-20
PLASTALUME®	STRIPS	1.57" x 18" White Foam	Class I/rule1	10626	2003-01-20
PLASTALUME®	STRIPS	2" x 16" Blue Foam	Class I/rule1	10631	2003-01-20
PLASTALUME®	STRIPS	2" x 16" White Foam	Class I/rule1	10632	2003-01-20
PLASTALUME®	STRIPS	2" x 18" White Foam	Class I/rule1	10635	2003-01-20
PLASTALUME®	STRIPS	3" x 16" Blue Foam	Class I/rule1	10641	2003-01-20
PLASTALUME®	STRIPS	3" x 16" White Foam	Class I/rule1	10642	2003-01-20
PLASTALUME®	STRIPS	4" x 16" Blue Foam	Class I/rule1	10651	2003-01-20
PLASTALUME®	STRIPS	4" x 16" White Foam	Class I/rule1	10652	2003-01-20
PLASTALUME®	STRIPS	1/2" x 9" Blue Foam	Class I/rule1	10661	2003-01-20
PLASTALUME®	STRIPS	1/2" x 9" White Foam	Class I/rule1	10662	2003-01-20
PLASTALUME®	STRIPS	3/4" x 9" Blue Foam	Class I/rule1	10671	2003-01-20
PLASTALUME®	STRIPS	3/4" x 9" White Foam	Class I/rule1	10672	2003-01-20
PLASTALUME®	STRIPS	1" x 9" Blue Foam	Class I/rule1	10681	2003-01-20
PLASTALUME®	STRIPS	1" x 9" White Foam	Class I/rule1	10682	2003-01-20
PLASTALUME®	DIGITALS	A-1 1 1/4" (33mm)	Class I/rule1	10101	2003-01-20
PLASTALUME®	DIGITALS	A-2 2 1/4" (58mm)	Class I/rule1	10102	2003-01-20
PLASTALUME®	DIGITALS	A-3 3 1/4" (83mm)	Class I/rule1	10103	2003-01-20
PLASTALUME®	DIGITALS	A-4 4 1/8" (106mm)	Class I/rule1	10104	2003-01-20

Device name	Make	Model	Risk class / rule <sup>1</sup>	P/N	First date of CE-Compliance
PLASTALUME®	DIGITALS	AB-4 3 1/4" (83mm)	Class I/rule1	10105	2003-01-20
PLASTALUME®	DIGITALS	AB-5 4 1/4" (110mm)	Class I/rule1	10106	2003-01-20
PLASTALUME®	DIGITALS	AB-6 5 1/4" (134mm)	Class I/rule1	10107	2003-01-20
PLASTALUME®	DIGITALS	AB-7 6 1/4" (160mm)	Class I/rule1	10108	2003-01-20
PLASTALUME®	DIGITALS	AB-8 7 1/4" (186mm)	Class I/rule1	10109	2003-01-20
PLASTALUME®	DIGITALS	AB-9 8 5/8" (220mm)	Class I/rule1	10110	2003-01-20
PLASTALUME®	ARMBOARDS	2 1/4" x 3/4"	Class I/rule1	SP 10410-25	2003-01-20
PLASTALUME®	ARMBOARDS	3 1/4" x 3/4"	Class I/rule1	SP 10415-25	2003-01-20
PLASTALUME®	ARMBOARDS	4" x 1"	Class I/rule1	SP 10411-25	2003-01-20
PLASTALUME®	ARMBOARDS	4 1/2" x 1 1/2"	Class I/rule1	SP 10414-25	2003-01-20
PLASTALUME®	ARMBOARDS	6" x 1 1/2"	Class I/rule1	SP 10416-25	2003-01-20
PLASTALUME®	ARMBOARDS	8" x 2 1/8"	Class I/rule1	SP 10417-25	2003-01-20
PLASTALUME®	ARMBOARDS	10" x 2 1/4"	Class I/rule1	SP 10418-25	2003-01-20
PLASTALUME®	ARMBOARDS w/ Stockinette	2 3/4" x 1"	Class I/rule1	SP 10452-25	2005-01-21
PLASTALUME®	ARMBOARDS w/ Stockinette	4" x 1"	Class I/rule1	SP 10431-25	2005-01-21
PLASTALUME®	ARMBOARDS w/Stockinette	4 1/2" x 1 1/2"	Class I/rule1	SP 10434-25	2005-01-21
PLASTALUME®	ARMBOARDS w/Stockinette	6" x 1 1/2"	Class I/rule1	SP 10436-25	2005-01-21
PLASTALUME®	ARMBOARDS w/Stockinette	8" x 2 1/8"	Class I/rule1	SP 10437-25	2005-01-21
PLASTALUME®	ARMBOARDS w/Stockinette	10" x 2 1/4"	Class I/rule1	SP 10438-25	2005-01-21
PLASTALUME®	ARMBOARDS PETG w/Stockinette	4" x 1"	Class I/rule1	SP 10441-25	2006-11-22
PLASTALUME®	ARMBOARDS PETG w/Stockinette	4 1/2" x 1 1/2"	Class I/rule1	SP 10444-25	2006-11-22
PLASTALUME®	ARMBOARDS PETG w/Stockinette	6" x 1 1/2"	Class I/rule1	SP 10446-25	2006-11-22
PLASTALUME®	ARMBOARDS PETG w/Stockinette	8" x 2 1/8"	Class I/rule1	SP 10447-25	2006-11-22
PLASTALUME®	ARMBOARDS PETG w/Stockinette	10" x 2 1/4"	Class I/rule1	SP 10448-25	2006-11-22
PLASTALUME®	Actimove® AluFoam Finger Splint	ACM ALF SPL FISP1.3CMX45.7 CM 12 INT.	Class I/rule1	72956-00000-03	2011-01-20
PLASTALUME®	Actimove® AluFoam Finger Splint	ACM ALF SPL FISP 1.9CMX45.7CM 12 INT.	Class I/rule1	72956-00001-03	2011-01-20
PLASTALUME®	Actimove® AluFoam Finger Splint	ACM ALF SPL FISP 2.5CMX45.7CM 12 INT.	Class I/rule1	72956-00002-03	2011-01-20
PLASTALUME®	BAR COLLES SPLINT	Small Right Pad	Class I/rule1	12811	2003-01-20
PLASTALUME®	BAR COLLES SPLINT	Small Left Pad	Class I/rule1	12813	2003-01-20
PLASTALUME®	BAR COLLES SPLINT	Medium Right Pad	Class I/rule1	12821	2003-01-20

Device name	Make	Model	Risk class / rule <sup>1</sup>	P/N	First date of CE-Compliance
PLASTALUME®	BAR COLLES SPLINT	Medium Left Pad	Class I/rule1	12823	2003-01-20
PLASTALUME®	BAR COLLES SPLINT	Large Right Pad	Class I/rule1	12831	2003-01-20
PLASTALUME®	BAR COLLES SPLINT	Large Left Pad	Class I/rule1	12833	2003-01-20
PLASTALUME®	CLASSIC FOREARM SPLINT	Small Right Pad	Class I/rule1	12111	2003-01-20
PLASTALUME®	CLASSIC FOREARM SPLINT	Small Left Pad	Class I/rule1	12113	2003-01-20
PLASTALUME®	CLASSIC FOREARM SPLINT	Medium Right Pad	Class I/rule1	12121	2003-01-20
PLASTALUME®	CLASSIC FOREARM SPLINT	Medium Left Pad	Class I/rule1	12123	2003-01-20
PLASTALUME®	CLASSIC FOREARM SPLINT	Large Right Pad	Class I/rule1	12131	2003-01-20
PLASTALUME®	CLASSIC FOREARM SPLINT	Large Left Pad	Class I/rule1	12133	2003-01-20
PLASTALUME®	COCKUP SPLINT	Small UnPad	Class I/rule1	12310	2003-01-20
PLASTALUME®	COCKUP SPLINT	Small Pad	Class I/rule1	12311	2003-01-20
PLASTALUME®	COCKUP SPLINT	Medium UnPad	Class I/rule1	12320	2003-01-20
PLASTALUME®	COCKUP SPLINT	Medium Pad	Class I/rule1	12321	2003-01-20
PLASTALUME®	COCKUP SPLINT	Large UnPad	Class I/rule1	12330	2003-01-20
PLASTALUME®	COCKUP SPLINT	Large Pad	Class I/rule1	12331	2003-01-20
PLASTALUME®	ANTERIOR ELBOW SPLINT	Small Pad	Class I/rule1	13211	2003-01-20
PLASTALUME®	ANTERIOR ELBOW SPLINT	Medium Pad	Class I/rule1	13221	2003-01-20
PLASTALUME®	ANTERIOR ELBOW SPLINT	Large Pad	Class I/rule1	13231	2003-01-20
PLASTALUME®	POSTERIOR ELBOW SPLINT	Small UnPad	Class I/rule1	13110	2003-01-20
PLASTALUME®	POSTERIOR ELBOW SPLINT	Small Pad	Class I/rule1	13111	2003-01-20
PLASTALUME®	POSTERIOR ELBOW SPLINT	Medium UnPad	Class I/rule1	13120	2003-01-20
PLASTALUME®	POSTERIOR ELBOW SPLINT	Medium Pad	Class I/rule1	13121	2003-01-20
PLASTALUME®	POSTERIOR ELBOW SPLINT	Large UnPad	Class I/rule1	13130	2003-01-20
PLASTALUME®	POSTERIOR ELBOW SPLINT	Large Pad	Class I/rule1	13131	2003-01-20
PLASTALUME®	POSTERIOR TIBIA/FIBULA SPLINT	Small 12" UnPad W/Foot	Class I/rule1	15010	2003-01-20
PLASTALUME®	POSTERIOR TIBIA/FIBULA SPLINT	Small 12" Pad W/Foot	Class I/rule1	15011	2003-01-20
PLASTALUME®	POSTERIOR TIBIA/FIBULA SPLINT	Small 12" UnPad WO/Foot	Class I/rule1	15110	2003-01-20
PLASTALUME®	POSTERIOR TIBIA/FIBULA SPLINT	Small 12" Pad WO/Foot	Class I/rule1	15111	2003-01-20
PLASTALUME®	POSTERIOR TIBIA/FIBULA SPLINT	Medium 14" UnPad W/Foot	Class I/rule1	15020	2003-01-20

Device name	Make	Model	Risk class / rule <sup>1</sup>	P/N	First date of CE-Compliance
PLASTALUME®	POSTERIOR TIBIA/FIBULA SPLINT	Medium 14" Pad W/Foot	Class I/rule1	15021	2003-01-20
PLASTALUME®	POSTERIOR TIBIA/FIBULA SPLINT	Medium 14" UnPad WO/Foot	Class I/rule1	15120	2003-01-20
PLASTALUME®	POSTERIOR TIBIA/FIBULA SPLINT	Medium 14" Pad WO/Foot	Class I/rule1	15121	2003-01-20
PLASTALUME®	POSTERIOR TIBIA/FIBULA SPLINT	Large 16" UnPad W/Foot	Class I/rule1	15030	2003-01-20
PLASTALUME®	POSTERIOR TIBIA/FIBULA SPLINT	Large 16" Pad W/Foot	Class I/rule1	15031	2003-01-20
PLASTALUME®	POSTERIOR TIBIA/FIBULA SPLINT	Large 16" UnPad WO/Foot	Class I/rule1	15130	2003-01-20
PLASTALUME®	POSTERIOR TIBIA/FIBULA SPLINT	Large 16" Pad WO/Foot	Class I/rule1	15131	2003-01-20
PLASTALUME®	POSTERIOR FEMUR SPLINT	Small 20" UnPad W/Foot	Class I/rule1	15210	2003-01-20
PLASTALUME®	POSTERIOR FEMUR SPLINT	Small 20" Pad W/Foot	Class I/rule1	15211	2003-01-20
PLASTALUME®	POSTERIOR FEMUR SPLINT	Small 20" UnPad WO/Foot	Class I/rule1	15310	2003-01-20
PLASTALUME®	POSTERIOR FEMUR SPLINT	Small 20" Pad WO/Foot	Class I/rule1	15311	2003-01-20
PLASTALUME®	POSTERIOR FEMUR SPLINT	Medium 25" UnPad W/Foot	Class I/rule1	15220	2003-01-20
PLASTALUME®	POSTERIOR FEMUR SPLINT	Medium 25" Pad W/Foot	Class I/rule1	15221	2003-01-20
PLASTALUME®	POSTERIOR FEMUR SPLINT	Medium 25" UnPad WO/Foot	Class I/rule1	15320	2003-01-20
PLASTALUME®	POSTERIOR FEMUR SPLINT	Medium 25" Pad WO/Foot	Class I/rule1	15321	2003-01-20
PLASTALUME®	POSTERIOR FEMUR SPLINT	Large 31" UnPad W/Foot	Class I/rule1	15230	2003-01-20
PLASTALUME®	POSTERIOR FEMUR SPLINT	Large 31" Pad W/Foot	Class I/rule1	15231	2003-01-20
PLASTALUME®	POSTERIOR FEMUR SPLINT	Large 31" UnPad WO/Foot	Class I/rule1	15330	2003-01-20
PLASTALUME®	POSTERIOR FEMUR SPLINT	Large 31" Pad WO/Foot	Class I/rule1	15331	2003-01-20
PLASTALUME®	COLLES SPLINT	Small Right UnPad	Class I/rule1	12010	2003-01-20
PLASTALUME®	COLLES SPLINT	Small Right Pad	Class I/rule1	12011	2003-01-20
PLASTALUME®	COLLES SPLINT	Small Left UnPad	Class I/rule1	12012	2003-01-20
PLASTALUME®	COLLES SPLINT	Small Left Pad	Class I/rule1	12013	2003-01-20
PLASTALUME®	COLLES SPLINT	Medium Right UnPad	Class I/rule1	12020	2003-01-20
PLASTALUME®	COLLES SPLINT	Medium Right Pad	Class I/rule1	12021	2003-01-20
PLASTALUME®	COLLES SPLINT	Medium Left UnPad	Class I/rule1	12022	2003-01-20
PLASTALUME®	COLLES SPLINT	Medium Left Pad	Class I/rule1	12023	2003-01-20

Device name	Make	Model	Risk class / rule <sup>1</sup>	P/N	First date of CE-Compliance
PLASTALUME®	COLLES SPLINT	Large Right UnPad	Class I/rule1	12030	2003-01-20
PLASTALUME®	COLLES SPLINT	Large Right Pad	Class I/rule1	12031	2003-01-20
PLASTALUME®	COLLES SPLINT	Large Left UnPad	Class I/rule1	12032	2003-01-20
PLASTALUME®	COLLES SPLINT	Large Left Pad	Class I/rule1	12033	2003-01-20
PLASTALUME®	MASON ALLEN HAND SPLINT	Small UnPad	Class I/rule1	12710	2003-01-20
PLASTALUME®	MASON ALLEN HAND SPLINT	Small Pad	Class I/rule1	12711	2003-01-20
PLASTALUME®	MASON ALLEN HAND SPLINT	Large UnPad	Class I/rule1	12730	2003-01-20
PLASTALUME®	MASON ALLEN HAND SPLINT	Large Pad	Class I/rule1	12731	2003-01-20
PLASTALUME®	METACARPAL SPLINT	Small Right Pad	Class I/rule1	12411	2003-01-20
PLASTALUME®	METACARPAL SPLINT	Small Left Pad	Class I/rule1	12413	2003-01-20
PLASTALUME®	METACARPAL SPLINT	Medium Right Pad	Class I/rule1	12421	2003-01-20
PLASTALUME®	METACARPAL SPLINT	Medium Left Pad	Class I/rule1	12423	2003-01-20
PLASTALUME®	METACARPAL SPLINT	Large Right Pad	Class I/rule1	12431	2003-01-20
PLASTALUME®	METACARPAL SPLINT	Large Left Pad	Class I/rule1	12433	2003-01-20
PLASTALUME®	PALM METACARPAL SPLINT	Small Right Pad	Class I/rule1	12511	2003-01-20
PLASTALUME®	PALM METACARPAL SPLINT	Small Left Pad	Class I/rule1	12513	2003-01-20
PLASTALUME®	PALM METACARPAL SPLINT	Medium Right Pad	Class I/rule1	12521	2003-01-20
PLASTALUME®	PALM METACARPAL SPLINT	Medium Left Pad	Class I/rule1	12523	2003-01-20
PLASTALUME®	PALM METACARPAL SPLINT	Large Right Pad	Class I/rule1	12531	2003-01-20
PLASTALUME®	PALM METACARPAL SPLINT	Large Left Pad	Class I/rule1	12533	2003-01-20
PLASTALUME®	SPEED HAND SPLINT	Small Right Pad	Class I/rule1	12911	2003-01-20
PLASTALUME®	SPEED HAND SPLINT	Small Left Pad	Class I/rule1	12913	2003-01-20
PLASTALUME®	SPEED HAND SPLINT	Medium Right Pad	Class I/rule1	12921	2003-01-20
PLASTALUME®	SPEED HAND SPLINT	Medium Left Pad	Class I/rule1	12923	2003-01-20
PLASTALUME®	SPEED HAND SPLINT	Large Right Pad	Class I/rule1	12931	2003-01-20
PLASTALUME®	SPEED HAND SPLINT	Large Left Pad	Class I/rule1	12933	2003-01-20
PLASTALUME®	UTILITY SPLINTS	3" x 10" (257mm) UnPad	Class I/rule1	12650	2003-01-20

Device name	Make	Model	Risk class / rule <sup>1</sup>	P/N	First date of CE-Compliance
PLASTALUME®	UTILITY SPLINTS	3" x 10" (257mm) Pad	Class I/rule1	12651	2003-01-20
PLASTALUME®	UTILITY SPLINTS	4" x 12" (308mm) UnPad	Class I/rule1	12660	2003-01-20
PLASTALUME®	UTILITY SPLINTS	4" x 12" (308mm) Pad	Class I/rule1	12661	2003-01-20
PLASTALUME®	LEWIN STERN	Universal finger	Class I/rule1	11301	2003-01-20
PLASTALUME®	BURNHAM SPLINT	Thumb right	Class I/rule1	11201	2003-01-20
PLASTALUME®	BURNHAM SPLINT	Thumb left	Class I/rule1	11211	2003-01-20
PLASTALUME®	BURNHAM SPLINT	Universal finger	Class I/rule1	11221	2003-01-20
PLASTALUME®	DIGIwrap™	Size 1	Class I/rule1	10321	2005-01-21
PLASTALUME®	DIGIwrap™	Size 2	Class I/rule1	10322	2005-01-21
PLASTALUME®	DIGIwrap™	Size 3	Class I/rule1	10323	2005-01-21
PLASTALUME®	DIGIwrap™	Size 4	Class I/rule1	10324	2005-01-21
PLASTALUME®	DIGIwrap™	Size 5	Class I/rule1	10325	2005-01-21
PLASTALUME®	DIGIwrap™	Size 6	Class I/rule1	10326	2005-01-21
PLASTALUME®	DIGIwrap™	Multi Pack	Class I/rule1	10327	2005-01-21
PLASTALUME®	DIGIwrap™ TOO	Size 1	Class I/rule1	10331	2005-01-21
PLASTALUME®	DIGIwrap™ TOO	Size 2	Class I/rule1	10332	2005-01-21
PLASTALUME®	DIGIwrap™ TOO	Size 3	Class I/rule1	10333	2005-01-21
PLASTALUME®	DIGIwrap™ TOO	Size 4	Class I/rule1	10334	2005-01-21
PLASTALUME®	DIGIwrap™ TOO	Size 5	Class I/rule1	10335	2005-01-21
PLASTALUME®	DIGIwrap™ TOO	Size 6	Class I/rule1	10336	2005-01-21
PLASTALUME®	DIGIwrap™ TOO	Multi Pack	Class I/rule1	10337	2005-01-21
<b>Group: SHOE</b>					
<b>INSERTS</b>					
Soft Stride™	BSP-S Bone Spur Pad	Small	Class I/rule1	71301	2005-01-21
Soft Stride™	BSP-M Bone Spur Pad	Medium	Class I/rule1	71302	2005-01-21
Soft Stride™	BSP-L Bone Spur Pad	Large	Class I/rule1	71303	2005-01-21
Soft Stride™	DBSP-S Bone Spur Pad Dispenser	Small	Class I/rule1	71306	2005-01-21
Soft Stride™	DBSP-M Bone Spur Pad Dispenser	Medium	Class I/rule1	71307	2005-01-21
Soft Stride™	DBSP-L Bone Spur Pad Dispenser	Large	Class I/rule1	71308	2005-01-21
Soft Stride™	EHC-S Extended Heel Cushion	Small	Class I/rule1	71311	2005-01-21
Soft Stride™	EHC-M Extended Heel Cushion	Medium	Class I/rule1	71312	2005-01-21
Soft Stride™	EHC-L Extended Heel Cushion	Large	Class I/rule1	71313	2005-01-21
Soft Stride™	DEHC-S Extended Heel Cushion Dispenser	Small	Class I/rule1	71316	2005-01-21
Soft Stride™	DEHC-M Extended Heel Cushion Dispenser	Medium	Class I/rule1	71317	2005-01-21
Soft Stride™	DEHC-L Extended Heel Cushion Dispenser	Large	Class I/rule1	71318	2005-01-21
Soft Stride™	DHE-U Hand Exerciser	Universal – 12/dispenser	Class I/rule1	71338	2005-01-21
Soft Stride™	HW-S Heel Wedge	Small	Class I/rule1	71341	2005-01-21
Soft Stride™	HW-M Heel Wedge	Medium	Class I/rule1	71342	2005-01-21
Soft Stride™	HW-L Heel Wedge	Large	Class I/rule1	71343	2005-01-21
Soft Stride™	LAP-S Longitudinal Arch Support Plain	Small	Class I/rule1	71351	2005-01-21

Device name	Make	Model	Risk class / rule <sup>1</sup>	P/N	First date of CE-Compliance
Soft Stride™	LAP-M Longitudinal Arch Support Plain	Medium	Class I/rule1	71352	2005-01-21
Soft Stride™	LAP-L Longitudinal Arch Support Plain	Large	Class I/rule1	71353	2005-01-21
Soft Stride™	LAV-S Longitudinal Arch Support T/C	Small	Class I/rule1	71356	2005-01-21
Soft Stride™	LAV-M Longitudinal Arch Support T/C	Medium	Class I/rule1	71357	2005-01-21
Soft Stride™	LAV-L Longitudinal Arch Support T/C	Large	Class I/rule1	71358	2005-01-21
Soft Stride™	MPP-S Metatarsal Pad Plain	Small	Class I/rule1	71361	2005-01-21
Soft Stride™	MPP-M Metatarsal Pad Plain	Medium	Class I/rule1	71362	2005-01-21
Soft Stride™	MPP-L Metatarsal Pad Plain	Large	Class I/rule1	71363	2005-01-21
Soft Stride™	MPV-S Metatarsal Pad T/C	Small	Class I/rule1	71366	2005-01-21
Soft Stride™	MPV-M Metatarsal Pad T/C	Medium	Class I/rule1	71367	2005-01-21
Soft Stride™	MPV-L Metatarsal Pad T/C	Large	Class I/rule1	71368	2005-01-21
Soft Stride™	SA-S MultiPad	Small	Class I/rule1	71371	2005-01-21
Soft Stride™	SA-M MultiPad	Medium	Class I/rule1	71372	2005-01-21
Soft Stride™	SA-L MultiPad	Large	Class I/rule1	71373	2005-01-21
Soft Stride™	DSA-S MultiPad Dispenser	Small – 12/dispenser	Class I/rule1	71376	2005-01-21
Soft Stride™	DSA-M MultiPad Dispenser	Medium – 12/dispenser	Class I/rule1	71377	2005-01-21
Soft Stride™	DSA-L MultiPad Dispenser	Large – 12/dispenser	Class I/rule1	71378	2005-01-21
Soft Stride™	PW-S Posting Wedge 6/pkg	Small	Class I/rule1	71381	2005-01-21
Soft Stride™	RDVS-1/4 Sheet Diamond T/C	1/4"	Class I/rule1	71406	2005-01-21
Soft Stride™	TFP-S Tenderfoot Pad	Small	Class I/rule1	71411	2005-01-21
Soft Stride™	TFP-M Tenderfoot Pad	Medium	Class I/rule1	71412	2005-01-21
Soft Stride™	TFP-L Tenderfoot Pad	Large	Class I/rule1	71413	2005-01-21
Soft Stride™	MTI-A Thin Insole T/C	Size A	Class I/rule1	71421	2005-01-21
Soft Stride™	MTI-B Thin Insole T/C	Size B	Class I/rule1	71422	2005-01-21
Soft Stride™	MTI-C Thin Insole T/C	Size C	Class I/rule1	71423	2005-01-21
Soft Stride™	MTI-D Thin Insole T/C	Size D	Class I/rule1	71424	2005-01-21
Soft Stride™	MTI-E Thin Insole T/C	Size E	Class I/rule1	71425	2005-01-21
Soft Stride™	UL-A Underliner	Size A	Class I/rule1	71430	2005-01-21
Soft Stride™	UL-B Underliner	Size B	Class I/rule1	71431	2005-01-21
Soft Stride™	UL-C Underliner	Size C	Class I/rule1	71432	2005-01-21
Soft Stride™	UL-D Underliner	Size D	Class I/rule1	71433	2005-01-21
Soft Stride™	UL-E Underliner	Size E	Class I/rule1	71434	2005-01-21
Soft Stride™	UL-F Underliner	Size F	Class I/rule1	71435	2005-01-21
Soft Stride™	UL-G Underliner	Size G	Class I/rule1	71436	2005-01-21
Soft Stride™	UL-H Underliner	Size H	Class I/rule1	71437	2005-01-21
Soft Stride™	UL-I Underliner	Size I	Class I/rule1	71438	2005-01-21
Soft Stride™	UL-J Underliner	Size J	Class I/rule1	71439	2005-01-21
Soft Stride™	INBSP-S Bone Spur Heel Pad IN	Small	Class I/rule1	71501	2005-01-21
Soft Stride™	INBSP-M Bone Spur Heel Pad IN	Medium	Class I/rule1	71502	2005-01-21
Soft Stride™	INBSP-L Bone Spur Heel Pad IN	Large	Class I/rule1	71503	2005-01-21



Device name	Make	Model	Risk class / rule <sup>1</sup>	P/N	First date of CE-Compliance
Soft Stride™	INHW-M Heel Wedge IN	Medium	Class I/rule1	71542	2005-01-21
Soft Stride™	INHW-L Heel Wedge IN	Large	Class I/rule1	71543	2005-01-21
Soft Stride™	INPNC-1/8 Sheet IN Plain	1/8"	Class I/rule1	71594	2005-01-21
Soft Stride™	INPNC-3/16 Sheet IN Plain	3/16"	Class I/rule1	71595	2005-01-21
Soft Stride™	INPWC-1/10 Sheet IN Plain T/C	1/10"	Class I/rule1	71601	2005-01-21
Soft Stride™	INPWC-1/4 Sheet IN Plain T/C	1/4"	Class I/rule1	71603	2005-01-21
Soft Stride™	INPWC-1/8 Sheet IN Plain T/C	1/8"	Class I/rule1	71604	2005-01-21
Soft Stride™	INPWC-3/16 Sheet IN Plain T/C	3/16"	Class I/rule1	71605	2005-01-21
Soft Stride™	INDWC-1/8 Sheet IN Diamond T/C	1/8"	Class I/rule1	71607	2005-01-21
Soft Stride™	INDWC-3/16 Sheet IN Diamond T/C	3/16"	Class I/rule1	71608	2005-01-21
Soft Stride™	OABSP-S Bone Spur Pad OA	Small	Class I/rule1	71701	2005-01-21
Soft Stride™	OABSP-M Bone Spur Pad OA	Medium	Class I/rule1	71702	2005-01-21
Soft Stride™	OABSP-L Bone Spur Pad OA	Large	Class I/rule1	71703	2005-01-21
Soft Stride™	OAHSP-S Bone Spur Heel Pad OA	Small	Class I/rule1	71706	2005-01-21
Soft Stride™	OAHSP-M Bone Spur Heel Pad OA	Medium	Class I/rule1	71707	2005-01-21
Soft Stride™	OAHSP-L Bone Spur Heel Pad OA	Large	Class I/rule1	71708	2005-01-21
Soft Stride™	PQBSP-S Bone Spur Heel Pad PQ	Small	Class I/rule1	71801	2005-01-21
Soft Stride™	PQBSP-M Bone Spur Heel Pad PQ	Medium	Class I/rule1	71802	2005-01-21
Soft Stride™	PQBSP-L Bone Spur Heel Pad PQ	Large	Class I/rule1	71803	2005-01-21
Soft Stride™	PQEHC-1/4-S Extended Heel Cushion PQ 1/4"	Small	Class I/rule1	71811	2005-01-21
Soft Stride™	PQEHC-1/4-M Extended Heel Cushion PQ 1/4"	Medium	Class I/rule1	71812	2005-01-21
Soft Stride™	PQEHC-1/4-L Extended Heel Cushion PQ 1/4"	Large	Class I/rule1	71813	2005-01-21
Soft Stride™	PQHW-S Heel Wedge PQ	Small	Class I/rule1	71841	2005-01-21
Soft Stride™	PQHW-M Heel Wedge PQ	Medium	Class I/rule1	71842	2005-01-21
Soft Stride™	PQHW-L Heel Wedge PQ	Large	Class I/rule1	71843	2005-01-21
Soft Stride™	PQTI-B Thin Insole PQ	Size B	Class I/rule1	71852	2005-01-21
Soft Stride™	PQTI-C Thin Insole PQ	Size C	Class I/rule1	71853	2005-01-21
Soft Stride™	PQTI-D Thin Insole PQ	Size D	Class I/rule1	71854	2005-01-21

Device name	Make	Model	Risk class / rule <sup>1</sup>	P/N	First date of CE-Compliance
Soft Stride™	BGBSP-S Bone Spur Pad BG	Small	Class I/rule1	71901	2005-01-21
Soft Stride™	BGBSP-M Bone Spur Pad BG	Medium	Class I/rule1	71902	2005-01-21
Soft Stride™	BGBSP-L Bone Spur Pad BG	Large	Class I/rule1	71903	2005-01-21
Soft Stride™	BGEHC-S Extended Heel Cushion BG	Small	Class I/rule1	71911	2005-01-21
Soft Stride™	BGEHC-M Extended Heel Cushion BG	Medium	Class I/rule1	71912	2005-01-21
Soft Stride™	BGEHC-L Extended Heel Cushion BG	Large	Class I/rule1	71913	2005-01-21
Soft Stride™	BGHW-S Heel Wedge BG	Small	Class I/rule1	71941	2005-01-21
Soft Stride™	BGHW-M Heel Wedge BG	Medium	Class I/rule1	71942	2005-01-21
Soft Stride™	BGHW-L Heel Wedge BG	Large	Class I/rule1	71943	2005-01-21
Soft Stride™	BGLAP-S Longitudinal Arch Support BG Plain	Small	Class I/rule1	71951	2005-01-21
Soft Stride™	BGLAP-M Longitudinal Arch Support BG Plain	Medium	Class I/rule1	71952	2005-01-21
Soft Stride™	BGLAP-L Longitudinal Arch Support BG Plain	Large	Class I/rule1	71953	2005-01-21
Soft Stride™	BGLAV-S Longitudinal Arch Support BG T/C	Small	Class I/rule1	71956	2005-01-21
Soft Stride™	BGLAV-M Longitudinal Arch Support BG T/C	Medium	Class I/rule1	71957	2005-01-21
Soft Stride™	BGLAV-L Longitudinal Arch Support BG T/C	Large	Class I/rule1	71958	2005-01-21
Soft Stride™	BGMPP-S Metatarsal Pad BG Plain	Small	Class I/rule1	71961	2005-01-21
Soft Stride™	BGMPP-M Metatarsal Pad BG Plain	Medium	Class I/rule1	71962	2005-01-21
Soft Stride™	BGMPP-L Metatarsal Pad BG Plain	Large	Class I/rule1	71963	2005-01-21
Soft Stride™	BGMPV-M Metatarsal Pad BG T/C	Medium	Class I/rule1	71967	2005-01-21
Soft Stride™	BGTFP-S Tenderfoot Pad BG	Small	Class I/rule1	72011	2005-01-21
Soft Stride™	BGTFP-M Tenderfoot Pad BG	Medium	Class I/rule1	72012	2005-01-21
Soft Stride™	BGTFP-L Tenderfoot Pad BG	Large	Class I/rule1	72013	2005-01-21
Soft Stride™	BGMTI-A Thin Insole BG T/C	Size A	Class I/rule1	72021	2005-01-21
Soft Stride™	BGMTI-B Thin Insole BG T/C	Size B	Class I/rule1	72022	2005-01-21
Soft Stride™	BGMTI-C Thin Insole BG T/C	Size C	Class I/rule1	72023	2005-01-21
Soft Stride™	BGMTI-D Thin Insole BG T/C	Size D	Class I/rule1	72024	2005-01-21
Soft Stride™	BGMTI-E Thin Insole BG T/C	Size E	Class I/rule1	72025	2005-01-21

Device name	Make	Model	Risk class / rule <sup>1</sup>	P/N	First date of CE-Compliance
Soft Stride™	BGUL-A Underliner BG	Size A	Class I/rule1	72030	2005-01-21
Soft Stride™	BGUL-B Underliner BG	Size B	Class I/rule1	72031	2005-01-21
Soft Stride™	BGUL-C Underliner BG	Size C	Class I/rule1	72032	2005-01-21
Soft Stride™	BGUL-D Underliner BG	Size D	Class I/rule1	72033	2005-01-21
<b>Group: Targeted Vibration</b>					
<b>Various Systems</b>					
Intellinetix®	Vibrating Back	Universal	Class I/rule12	07239	2019-06-03
Intellinetix®	Vibrating Calf/Shin	Universal	Class I/rule12	07237	2019-06-03
Intellinetix®	Vibrating Foot/Ankle	Universal	Class I/rule12	07242	2019-06-03
Intellinetix®	Vibrating Glove	Small	Class I/rule12	07230	2019-06-03
Intellinetix®	Vibrating Glove	Medium	Class I/rule12	07231	2019-06-03
Intellinetix®	Vibrating Glove	Large	Class I/rule12	07232	2019-06-03
Intellinetix®	Vibrating Headach Band	Universal	Class I/rule12	07238	2019-06-03
Intellinetix®	Vibrating Knee/Elbow	Universal	Class I/rule12	07235	2019-06-03
Intellinetix®	Vibrating Mask	Universal	Class I/rule12	07236	2019-06-03
Intellinetix®	Vibrating Quad/Thigh	Universal	Class I/rule12	07241	2019-06-03
Intellinetix®	Vibrating Universal Wrap	Universal	Class I/rule12	07240	2019-06-03
Intellinetix®	Step Sensor	Universal	Class I/rule1	07105	2013-12-04