

DECLARATION OF CONFORMITY

DER.DOC.146 MDR

Technical File: Upper Extremity Supports and Braces

This declaration is issued under the sole responsibility of

**DeRoyal Industries Inc. 200 DeBusk Lane, Powell, TN 37849 USA
SRN# US-MF-000002102**

European authorized representative	Notified Body
Emergo Europe. Princessegracht 20 2514 AP The Hague The Netherlands SRN NL-AR-000000116	[EXCLUSION - Class 1 non sterile]

Product Codes: attached Appendix A:

Risk Classification: Class I, Rule 1

GMDN Code: 41458, 16210, 12101, 41053, 12095

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

Document No.	Title	Edition / Date of issue
EU 2017/745	Medical Device Regulation	2017-04-05

The above identified products, at the stated revisions where applicable, have been reviewed against the relevant provisions of the Medical Device Regulation, as amended, and have been found to be in compliance with Article 19, Annex IV, as well as the National Laws for countries where these products are made available. These products are also manufactured according to a quality system certified to the ISO 13485: 2016 standard.

Oct 28, 2021

(Date of Issue)

Powell, Tennessee
(Place of Issue)



Manufacturer Signature

Assistant Director of Regulatory Affairs
(Function of Manufacturer)

Appendix A: Schedule of Product

Product Number	Label Description	Intended Purpose	Basic UDI	
11650005	Shoulder Abduction Device Small	The DeRoyal® Shoulder Abduction Device is intended for patients recuperating from rotator cuff repair, Bankart repairs, soft tissue repairs, shoulder sprains and strains, acute shoulder instability and reconstruction.	07497561469L	
11650006	Shoulder Abduction Device Shoulder Abduction Device		07497561469L	
11650007	Shoulder Abduction Device Large		07497561469L	
11690001	Arm Sling Infant Print	The Arm Sling is used for cast support, injuries to the arm, wrist or hand, acromioclavicular sprains, and anterior glenohumeral dislocations.	07497561469L	
11690002	Arm Sling Canvas with Shoulder Pad		07497561469L	
11690005	Arm Sling Deluxe with Shoulder Pad		07497561469L	
11690006	Arm Sling Deluxe with Shoulder Pad		07497561469L	
11690007	Arm Sling Deluxe with Shoulder Pad		07497561469L	
11690008	Arm Sling Deluxe with Shoulder Pad		07497561469L	
125BL	Arm Sling Deluxe with Shoulder Pad		The DeRoyal® Resting Hand Splint is intended for post-surgery/ injury positioning, wrist drop or finger flexor tightness.	07497561469L
125BR	Wire Foam Resting Splint Resting Hand Splint			07497561469L
125CL	Wire Foam Resting Splint Resting Hand Splint	07497561469L		
125CR	Wire Foam Resting Splint Resting Hand Splint	07497561469L		
125DL	Wire Foam Resting Splint Resting Hand Splint	07497561469L		
202BL	Hand Splint Ulnar Deviation/ Arthritis Splint	The DeRoyal® Hand Splint is used to support and position the fingers affected by joint changes which have resulted in ulnar deviation of the digits. This splint is recommended for the arthritic patient who requires metacarpophalangeal and ulnar support of the digits, but has wrist stability.	07497561469L	
202BR	Hand Splint Ulnar Deviation/ Arthritis Splint		07497561469L	
202CL	Hand Splint Ulnar Deviation/ Arthritis Splint		07497561469L	
202CR	Hand Splint Ulnar Deviation/ Arthritis Splint		07497561469L	



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Product Number	Label Description	Intended Purpose	Basic UDI
202DL	Hand Splint Ulnar Deviation/ Arthritis Splint		07497561469L
202DR	Hand Splint Ulnar Deviation/ Arthritis Splint		07497561469L
325BL	Hand Splint Air Soft, Resting	The DeRoyal® Resting Hand Splint is intended for post-surgery or injury positioning, wrist drop and finger flexor tightness.	07497561469L
325BR	Hand Splint Air Soft, Resting		07497561469L
325CL	Hand Splint Air Soft, Resting		07497561469L
325CR	Hand Splint Air Soft, Resting		07497561469L
325DL	Hand Splint Air Soft, Resting		07497561469L
325DR	Hand Splint Air Soft, Resting		07497561469L
403-CL	Replacement Softgoods Kit Air Short Opponents Inflatable Hand Orthosis	The DeRoyal® Pucci® Air Short Opponents Inflatable Hand Orthosis is intended to provide continuous low stretch therapy to the contracted hand.	07497561469L
403-CR	Replacement Softgoods Kit Air Short Opponents Inflatable Hand Orthosis		07497561469L
403L	Pucci Air Hand Orthosis Short Opponents		07497561469L
403PL	Pucci Air Hand Orthosis Short Opponents - Pediatric		07497561469L
403PR	Pucci Air Hand Orthosis Short Opponents - Pediatric		07497561469L
403PSL	Pucci Air Hand Orthosis Short Opponents - Pediatric		07497561469L
403PSR	Pucci Air Hand Orthosis Short Opponents - Pediatric		07497561469L
403R	Pucci Air Hand Orthosis Short Opponents		07497561469L
405-CL	Replacement Softgoods Kit Inflatable Hand Orthosis		The DeRoyal® Pucci® Air-T Inflatable Hand Orthosis is intended to provide continuous low stretch therapy to the contracted hand.
405-CR	Replacement Softgoods Kit Inflatable Hand Orthosis	07497561469L	



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Product Number	Label Description	Intended Purpose	Basic UDI
405L	Inflatable Hand Orthosis Pucci		07497561469L
405PL	Inflatable Hand Orthosis Pediatric		07497561469L
405PR	Inflatable Hand Orthosis Pediatric		07497561469L
405R	Inflatable Hand Orthosis Pucci		07497561469L
411L	Hand Orthosis Pucci	The DeRoyal® Pucci® EZE Hand Orthosis is intended to provide continuous therapy to the contracted fingers, hand and wrist.	07497561469L
411PL	Hand Orthosis Pediatric		07497561469L
411PR	Hand Orthosis Pediatric		07497561469L
411R	Hand Orthosis Pucci		07497561469L
4125CK	Elbow Orthosis Replacement Pads	The Pro-Glide™ Dynamic Elbow ROM Orthosis was designed for the treatment of joint stiffness and established soft tissue contractures which may have resulted from trauma or immobilization. Protocols for use vary depending on the diagnosis and should be determined after consulting with the patient's physician. This orthosis combines flexion and extension modes in a single unit. Each orthosis is delivered in an extension mode.	07497561469L
4125CL	Elbow Orthosis Range of Motion		07497561469L
4125CR	Elbow Orthosis Range of Motion		07497561469L
4125DK	Elbow Orthosis Replacement Pads		07497561469L
4125DL	Elbow Orthosis Range of Motion		07497561469L
4125DR	Elbow Orthosis Range of Motion		07497561469L
4127BK	PRO-GLIDE ELBOW JR. ORTHOSIS Replacement Softgoods Kit		07497561469L
4127BL	Elbow Orthosis / Pediatric Range of Motion		07497561469L
4127BR	Elbow Orthosis / Pediatric Range of Motion		07497561469L
4127CK	PRO-GLIDE ELBOW JR. ORTHOSIS Replacement Softgoods Kit		07497561469L
4127CL	Elbow Orthosis / Pediatric Range of Motion		07497561469L
4127CR	Elbow Orthosis / Pediatric Range of Motion		07497561469L
4127DK	PRO-GLIDE ELBOW JR. ORTHOSIS Replacement Softgoods Kit		07497561469L
4127DL	Elbow Orthosis / Pediatric Range of		07497561469L



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Product Number	Label Description	Intended Purpose	Basic UDI
	Motion		
4127DR	Elbow Orthosis / Pediatric Range of Motion		07497561469L
413-CL	Replacement Softgoods Kit Air Inflatable Hand Orthosis	The DeRoyal® Pucci® Air Inflatable Hand Orthosis is intended to provide continuous low stretch therapy to the contracted hand.	07497561469L
413-CR	Replacement Softgoods Kit Air Inflatable Hand Orthosis		07497561469L
413L	Air Inflatable Hand Orthosis Pucci		07497561469L
413PL	Air Inflatable Hand Orthosis Pediatric		07497561469L
413PR	Air Inflatable Hand Orthosis Pediatric		07497561469L
413R	Air Inflatable Hand Orthosis Pucci		07497561469L
415-CL	Replacement Softgoods Kit Reflex Inbibitory Position Hand Orthosis		The DeRoyal® Pucci® Reflex Inhibitory Position (R.I.P.) Hand Orthosis is intended to provide continuous therapy to the contracted fingers, hand and wrist.
415-CR	Replacement Softgoods Kit Reflex Inbibitory Position Hand Orthosis	07497561469L	
415L	Reflex Inhibitory Position Hand Orthosis	07497561469L	
415PL	Reflex Inhibitory Position Hand Orthosis Pediatric	07497561469L	
415PR	Reflex Inhibitory Position Hand Orthosis Pediatric	07497561469L	
415R	Reflex Inhibitory Position Hand Orthosis	07497561469L	
4229CL	DEROM ELBOW ORTHOSIS Range of Motion	The DeRoyal® Range Of Motion (DeROM®) Dynamic Elbow Orthosis was designed for the treatment of joint stiffness, and established soft tissue contractures, which may have resulted from trauma, immobilization, or neurological disorders. Protocols for use vary depending on the diagnosis and should be determined after	
4229CLK	DEROM ELBOW ORTHOSIS Replacement Pads		07497561469L
4229CR	DEROM ELBOW ORTHOSIS Range of Motion		07497561469L



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Product Number	Label Description	Intended Purpose	Basic UDI
4229CRK	DEROM ELBOW ORTHOSIS Replacement Pads	consulting with the patient's physician.	07497561469L
4229DL	DEROM ELBOW ORTHOSIS Range of Motion		07497561469L
4229DLK	DEROM ELBOW ORTHOSIS Replacement Pads		07497561469L
4229DR	DEROM ELBOW ORTHOSIS Range of Motion		07497561469L
4229DRK	DEROM ELBOW ORTHOSIS Replacement Pads		07497561469L
4415L	STATIC-PRO WRIST ORTHOSIS Range of Motion	The DeRoyal® Static-Pro® Wrist Orthosis is intended to treat joint stiffness, and established soft tissue contractures, which may have resulted from trauma, immobilization, or neurological disorders. The Static-Pro® assists in either flexion or extension in one unit.	07497561469L
4415R	STATIC-PRO WRIST ORTHOSIS Range of Motion		07497561469L
4425L	STATIC-PRO ELBOW ORTHOSIS Range of Motion	The DeRoyal® Static-Pro® Elbow Orthosis was designed for the treatment of joint stiffness, and established soft tissue contractures, which may have resulted from trauma, immobilization, or neurological disorders. The Static-Pro® Orthosis assists with either flexion or extension in one unit.	07497561469L
4425LML	STATIC-PRO ELBOW ORTHOSIS Replacement Softgoods Kit		07497561469L
4425LMR	STATIC-PRO ELBOW ORTHOSIS Replacement Softgoods Kit		07497561469L
4425R	STATIC-PRO ELBOW ORTHOSIS Range of Motion		07497561469L
501A	Finger Spring Extension Assist	The DeRoyal® Finger Spring fits from the head of the metacarpal to the distal interphalangeal joint. It is used to assist the proximal interphalangeal joint (PIP) into increased extension. It has a minimal effect on metacarpophalangeal (MP) extension.	07497561469L
501AA	Finger Spring Extension Assist		07497561469L
501B	Finger Spring Extension Assist		07497561469L
501C	Finger Spring Extension Assist		07497561469L
501D	Finger Spring Extension Assist		07497561469L
502A	Finger Spring Coil Extension	The DeRoyal® Finger Spring fits from the head of the metacarpal to the distal interphalangeal joint. The coil	07497561469L
502B	Finger Spring Coil Extension		07497561469L



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Product Number	Label Description	Intended Purpose	Basic UDI
502C	Finger Spring Coil Extension	springs, at the lateral aspect of the proximal interphalangeal joint (PIP) act to increase PIP extension while allowing active flexion.	07497561469L
502D	Finger Spring Coil Extension		07497561469L
503A	Finger Spring Coil Flexion	The DeRoyal® Finger Spring fits from the base of the proximal phalanx to the distal interphalangeal joint. The coil springs, at the lateral aspect of the proximal interphalangeal joint (PIP), act to increase PIP flexion while allowing active extension. The distal phalanx is free to allow functional use of the finger pad.	07497561469L
503B	Finger Spring Coil Flexion		07497561469L
503C	Finger Spring Coil Flexion		07497561469L
503D	Finger Spring Coil Flexion		07497561469L
504A	Finger Spring PIP Extension Assist	The DeRoyal® Finger Spring fits from the proximal phalanx to the distal interphalangeal (DIP) joint. It is used to assist the proximal interphalangeal joint (PIP) into increased extension. It does not interfere with the metacarpophalangeal (MP) joint	07497561469L
504AA	Finger Spring PIP Extension Assist		07497561469L
504B	Finger Spring PIP Extension Assist		07497561469L
504C	Finger Spring PIP Extension Assist		07497561469L
504D	Finger Spring PIP Extension Assist		07497561469L
507A	Finger Spring Acu-Spring Extension Assist	The DeRoyal® Finger Spring fits from the head of the metacarpal to the distal interphalangeal joint. It is used to assist the proximal interphalangeal joint (PIP) into increased extension. It has a minimal effect on metacarpophalangeal (MP) extension	07497561469L
507AA	Finger Spring Acu-Spring Extension Assist		07497561469L
507B	Finger Spring Acu-Spring Extension Assist		07497561469L
507C	Finger Spring Acu-Spring Extension Assist		07497561469L
507D	Finger Spring Acu-Spring Extension Assist		07497561469L
508A	Finger Spring Acu-Spring PIP Extension Assist	The DeRoyal® Finger Spring fits from the proximal phalanx to the distal interphalangeal (DIP) joint. It is used to assist the proximal interphalangeal (PIP) joint into increased extension. It has a minimal effect on metacarpophalangeal (MP) extension	07497561469L
508AA	Finger Spring Acu-Spring PIP Extension Assist		07497561469L
508B	Finger Spring Acu-Spring PIP Extension Assist		07497561469L



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Product Number	Label Description	Intended Purpose	Basic UDI
508C	Finger Spring Acu-Spring PIP Extension Assist		07497561469L
508D	Finger Spring Acu-Spring PIP Extension Assist		07497561469L
601A	Finger Spring Low Tension Flexion	The DeRoyal® Finger Splint fits from the head of the proximal phalanx to the distal interphalangeal (DIP) joint. This splint provides a light tension at the proximal interphalangeal (PIP) joint, to position the PIP joint in a flexed position. The distal phalanx is free to allow functional use of the finger pad	07497561469L
601AA	Finger Spring Low Tension Flexion		07497561469L
601B	Finger Spring Low Tension Flexion		07497561469L
601C	Finger Spring Low Tension Flexion		07497561469L
601D	Finger Spring Low Tension Flexion		07497561469L
602A	Finger Spring Low Tension Extension	The DeRoyal® Finger Spring fits from the base of the proximal phalanx to the distal interphalangeal (DIP) joint. This splint acts to extend the proximal interphalangeal (PIP) joint and allow active DIP flexion. The smaller sizes can be used to extend the DIP joint.	07497561469L
602AA	Finger Spring Low Tension Extension		07497561469L
602B	Finger Spring Low Tension Extension		07497561469L
602C	Finger Spring Low Tension Extension		07497561469L
602D	Finger Spring Low Tension Extension		07497561469L
620	Finger Splint Stax	The DeRoyal® Finger Splint protects the distal phalanx and extends the distal interphalangeal (DIP) joint.	07497561469L
621	Finger Splint Stax		07497561469L
622	Finger Splint Stax		07497561469L
623	Finger Splint Stax		07497561469L
6235	Finger Splint Stax		07497561469L
624	Finger Splint Stax		07497561469L
625	Finger Splint Stax		07497561469L
6255	Finger Splint Stax		07497561469L
626	Finger Splint Stax		07497561469L
627	Finger Splint Stax		07497561469L
630	Finger Splint Assortment		07497561469L
635	Finger Splint Stax		07497561469L
640	Finger Splint Stax		07497561469L
645	Stax Finger Splint		07497561469L



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Product Number	Label Description	Intended Purpose	Basic UDI
670AABLK	Finger Splint	The DeRoyal® Finger Splint is intended for finger flexion tightness following tendon repair and injury, swelling and tightness following finger fractures and sprains, following boutonniere surgery and deformity, swan neck deformity, mallet finger (with static strut), and for protection and comfort during the inflammatory phase of arthritis or tendonitis.	07497561469L
670ABLK	Finger Splint		07497561469L
670BBLK	Finger Splint		07497561469L
670CBLK	Finger Splint		07497561469L
670DBLK	Finger Splint		07497561469L
701B	Hand Splint Middle Phalanx, Flexion	The DeRoyal® Hand Splint dynamically flexes metacarpophalangeal (MP) joints and is intended to address tightness or tendency to extend MP joints following wrist fracture.	07497561469L
701C	Hand Splint Middle Phalanx, Flexion		07497561469L
701D	Hand Splint Middle Phalanx, Flexion		07497561469L
707BL	Wrist Support	The DeRoyal® Wrist Support combines dynamic wrist extension and metacarpophalangeal (MP) flexion. This support features thumb abduction and interphalangeal extension assists. The Wrist Support is indicated for post wrist fracture, tendon or nerve injuries or crush injuries.	07497561469L
707BR	Wrist Support		07497561469L
707CL	Wrist Support		07497561469L
707CR	Wrist Support		07497561469L
707DL	Wrist Support		07497561469L
707DR	Wrist Support		07497561469L
708BL	Wrist Support	The DeRoyal® Wrist Support uses wire coils at the wrist joint axis to assist the wrist and digits into extension. The thumb outrigger assists the thumb into abduction/extension. This splint is recommended in injuries involving the radial nerve	07497561469L
708BR	Wrist Support		07497561469L
708CL	Wrist Support		07497561469L
708CR	Wrist Support		07497561469L
708DL	Wrist Support		07497561469L
708DR	Wrist Support	07497561469L	
711BL	Hand Splint	The DeRoyal® Hand Splint is designed to prevent hyperextension of the ring and small fingers after an ulnar nerve injury. The design provides a light metacarpophalangeal block to the digits and allows full dynamic function of the hand.	07497561469L
711BR	Hand Splint		07497561469L
711CL	Hand Splint		07497561469L
711CR	Hand Splint		07497561469L
711DL	Hand Splint		07497561469L
711DR	Hand Splint		07497561469L



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Product Number	Label Description	Intended Purpose	Basic UDI
8004-01	Arm Sling SPECIALTY	The Arm Sling is used for cast support, injuries to the arm, wrist or hand, acromioclavicular sprains, and anterior glenohumeral dislocations.	07497561469L
8004-02	Arm Sling Canvas with Shoulder Pad		07497561469L
8004-03	Arm Sling Canvas with Shoulder Pad		07497561469L
8004-04	Arm Sling Canvas with Shoulder Pad		07497561469L
8004-04B	Arm Sling		07497561469L
8004-05	Arm Sling Canvas with Shoulder Pad		07497561469L
8004-05B	Arm Sling		07497561469L
8004-06	Arm Sling Canvas with Shoulder Pad		07497561469L
812	Finger Separator	The DeRoyal® Pucci® Finger Separator is intended to help position mild to moderate contracted or deviated fingers	07497561469L
812P	Finger Separator Pediatric		07497561469L
EB6000-01	WARRIOR ELBOW POST-OPERATIVE BRACE	Warrior Post-Operative Elbow Braces are used for Post-operative rehabilitation; Olecranon fractures; Radial head fractures; Hairline fracture of the radius, humerus and ulna; Ligamentous reconstruction procedures of the elbow	07497561469L
EB6000-02	WARRIOR ELBOW POST-OPERATIVE BRACE		07497561469L
EU00326100409	Air Soft Resting Handsplint Left, SM	The DeRoyal® Resting Hand Splint is intended for post surgery or injury positioning, wrist drop and finger flexor tightness.	07497561469L
EU00326100509	Air Soft Resting Handsplint Left, MD		07497561469L
EU00326100609	Air Soft Resting Handsplint Left, LG		07497561469L
EU00326100709	Air Soft Resting Handsplint Left, XL		07497561469L
EU00326140409	MANU-HiT® Digitus Pollex Left, Small		07497561469L
EU00326140509	MANU-HiT® Digitus Pollex Left, Medium		07497561469L
EU00326140609	MANU-HiT® Digitus Pollex Left, Large		07497561469L
EU00326200409	Air Soft Resting Handsplint Right, SM		07497561469L
EU00326200509	Air Soft Resting Handsplint Right, MD		07497561469L
EU00326200609	Air Soft Resting Handsplint Right, LG		07497561469L
EU00326200709	Air Soft Resting Handsplint Right, XL		07497561469L
EU00326240409	MANU-HiT® Digitus Pollex Right,		07497561469L



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Product Number	Label Description	Intended Purpose	Basic UDI
	Small		
EU00326240509	MANU-HiT® Digitus Pollex Right, Medium		07497561469L
EU00326240609	MANU-HiT® Digitus Pollex Right, Large		07497561469L
EU00403101109	MANU-HiT® AIR ROLL Left	The DeRoyal® Pucci® Air Short Opponens Inflatable Hand Orthosis is intended to provide continuous low stretch therapy to the contracted hand.	07497561469L
EU00403130107	Hand Pucci® Air Short,Opponens Left		07497561469L
EU00403130307	Hand Pucci® Air Short,Opponens Pediatric, Left, Regular		07497561469L
EU00403131107	Hand Pucci® Air Short,Opponens Cover		07497561469L
EU00403201109	MANU-HiT® AIR ROLL Right		07497561469L
EU00403230107	Hand Pucci® Air Short,Opponens Right		07497561469L
EU00403230307	Hand Pucci® Air Short,Opponens Pediatric, Right, Regular		07497561469L
EU00403231107	Hand Pucci® Air Short,Opponens Cover		07497561469L
EU00403231307	Hand Pucci Air Short, Opponens Pediatric Cover		07497561469L
EU00405101109	MANU-HiT® AIR T Left, Adult		The DeRoyal® Pucci® Air-T Inflatable Hand Orthosis is intended to provide continuous low stretch therapy to the contracted hand.
EU00405101209	MANU-HiT® AIR T Left, Adult, X-Long	07497561469L	
EU00405130107	Hand Pucci® Air-T Left, Adult	07497561469L	
EU00405130207	Hand Pucci® Air-T Left, Adult, X-Long	07497561469L	
EU00405130307	Hand Pucci® Air-T Left, Pediatric	07497561469L	
EU00405130312	Hand Pucci® Air-T Left, Pediatric, Snowtiger	07497561469L	
EU00405201109	MANU-HiT® AIR T Right, Adult	07497561469L	
EU00405201209	MANU-HiT® AIR T Right, Adult, X-Long	07497561469L	



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Product Number	Label Description	Intended Purpose	Basic UDI
EU00405230107	Hand Pucci® Air-T Right, Adult		07497561469L
EU00405230207	Hand Pucci® Air-T Right, Adult, X-Long		07497561469L
EU00405230307	Hand Pucci® Air-T Right, Pediatric		07497561469L
EU00405230312	Hand Pucci® Air-T Right, Pediatric, Snowtiger		07497561469L
EU00405231312	Hand Pucci® Air T Coverv Pediatric Snowtiger		07497561469L
EU00411130107	Hand Pucci® EZE Left	The DeRoyal® Pucci® EZE Hand Orthosis is intended to provide continuous therapy to the contracted fingers, hand and wrist.	07497561469L
EU00411130307	Hand Pucci® EZE Pediatric, Left		07497561469L
EU00411131107	Pucci Cover Left EZE	The DeRoyal® Pucci® EZE Hand Orthosis is intended to provide continuous therapy to the contracted fingers, hand and wrist.	07497561469L
EU00411230107	Hand Pucci® EZE Right		07497561469L
EU00411230307	Hand Pucci® EZE Pediatric, Right		07497561469L
EU00411231107	Hand Pucci EZE Cover		07497561469L
EU00411231307	Hand Pucci EZE Cover /Pediatric		07497561469L
EU00413101109	MANU-HiT® AIR Left	The DeRoyal® Pucci® Air Inflatable Hand Orthosis is intended to provide continuous low stretch therapy to the contracted hand.	07497561469L
EU00413101209	MANU-HiT® AIR Adult, X-Long, Left		07497561469L
EU00413130107	Hand Pucci® Air Left		07497561469L
EU00413130207	Hand Pucci® Air Adult, X-Long, Left		07497561469L
EU00413130307	Hand Pucci® Air Left, Pediatric		07497561469L
EU00413130312	Hand Pucci® Air Left, Pediatric, Snowtiger		07497561469L
EU00413131207	Pucci Cover Left, X-Long		07497561469L
EU00413201109	MANU-HiT® AIR Right		07497561469L
EU00413201209	MANU-HiT® Air Adult, X-Long, Right		07497561469L
EU00413230107	Hand Pucci® Air Right		07497561469L
EU00413230207	Hand Pucci® Air Adult, X-Long, Right		07497561469L
EU00413230307	Hand Pucci® Air Right, Pediatric		07497561469L



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Product Number	Label Description	Intended Purpose	Basic UDI
EU00413230312	Hand Pucci® Air Right, Pediatric, Snowtiger		07497561469L
EU00413231207	Hand Pucci® Air Cover Cover		07497561469L
EU00413231307	Hand Pucci® Air Pediatric Cover		07497561469L
EU00413231312	Hand Pucci® Air Cover, Pediatric, Snowtiger		07497561469L
EU02014-L3	Thumb Splint, Basic Mid Length	This DeRoyal® Thumb Splint is intended to provide support to the CMC and MP joints of the thumb.	07497561469L
EU02014-L4	Thumb Splint, Basic Mid Length		07497561469L
EU02014-L5	Thumb Splint, Basic Mid Length		07497561469L
EU02014-L6	Thumb Splint, Basic Mid Length		07497561469L
EU02014-L7	Thumb Splint, Basic Mid Length		07497561469L
EU02014-R3	Thumb Splint, Basic Mid Length		07497561469L
EU02014-R4	Thumb Splint, Basic Mid Length		07497561469L
EU02014-R5	Thumb Splint, Basic Mid Length		07497561469L
EU02014-R6	Thumb Splint, Basic Mid Length		07497561469L
EU02014-R7	Thumb Splint, Basic Mid Length		07497561469L
EU02014100303	Thumb Splint, Basic Mid Black, Left, X-Small		07497561469L
EU02014100403	Thumb Splint, Basic Mid Black, Left, Small		07497561469L
EU02014100503	Thumb Splint, Basic Mid Black, Left, Medium		07497561469L
EU02014100603	Thumb Splint, Basic Mid Black, Left, Large		07497561469L
EU02014100703	Thumb Splint, Basic Mid Black, Left, X-Large		07497561469L
EU02014200303	Thumb Splint, Basic Mid Beige, Left, X-Small		07497561469L
EU02014200403	Thumb Splint, Basic Mid Beige, Left, Small		07497561469L



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Product Number	Label Description	Intended Purpose	Basic UDI
EU02014200503	Thumb Splint, Basic Mid Beige, Left, Medium		07497561469L
EU02014200603	Thumb Splint, Basic Mid Beige, Left, Large		07497561469L
EU02014200703	Thumb Splint, Basic Mid Beige, Left, X-Large		07497561469L
EU02028100303	Wrist Splint, Lace-Up Beige, Left, X-Small	Mild sprains and strains of the wrist; Tendonitis; Carpal tunnel syndrome; Overuse injuries; Tenosynovitis.	07497561469L
EU02028100403	Wrist Splint, Lace-Up Beige, Left, Small		07497561469L
EU02028100503	Wrist Splint, Lace-Up Beige, Left, Medium		07497561469L
EU02028100603	Wrist Splint, Lace-Up Beige, Left, Large		07497561469L
EU02028100703	Wrist Splint, Lace-Up Beige, Left, X-Large		07497561469L
EU02028100803	Wrist Splint, Lace-Up Beige, Left, XX-Large		07497561469L
EU02028200303	Wrist Splint, Lace-Up Beige, Right, X-Small		07497561469L
EU02028200403	Wrist Splint, Lace-Up Beige, Right, Small		07497561469L
EU02028200503	Wrist Splint, Lace-Up Beige, Right, Medium		07497561469L
EU02028200603	Wrist Splint, Lace-Up Beige, Right, Large		07497561469L
EU02028200703	Wrist Splint, Lace-Up Beige, Right, X-Large		07497561469L
EU02028200803	Wrist Splint, Lace-Up Beige, Right, XX-Large		07497561469L
EU02029100309	Wrist Splint, Lace-Up Black, Left, X-		07497561469L



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Product Number	Label Description	Intended Purpose	Basic UDI	
	Small			
EU02029100409	Wrist Splint, Lace-Up Black, Left, Small		07497561469L	
EU02029100509	Wrist Splint, Lace-Up Black, Left, Medium		07497561469L	
EU02029100609	Wrist Splint, Lace-Up Black, Left, Large		07497561469L	
EU02029100709	Wrist Splint, Lace-Up Black, Left, X-Large		07497561469L	
EU02029100809	Wrist Splint, Lace-Up Black, Left, XX-Large		07497561469L	
EU02029200309	Wrist Splint, Lace-Up Black, Right, X-Small		07497561469L	
EU02029200409	Wrist Splint, Lace-Up Black, Right, Small		07497561469L	
EU02029200509	Wrist Splint, Lace-Up Black, Right, Medium		07497561469L	
EU02029200609	Wrist Splint, Lace-Up Black, Right, Large		07497561469L	
EU02029200709	Wrist Splint, Lace-Up Black, Right, X-Large		07497561469L	
EU02029200809	Wrist Splint, Lace-Up Black, Right, XX-Large		07497561469L	
EU02055100309	Wrist Splint Black, Left, X-Small		This DeRoyal® Thumb Splint is intended to provide support to the CMC and MP joints of the thumb	07497561469L
EU02055100409	Wrist Splint Black, Left, Small			07497561469L
EU02055100509	Wrist Splint Black, Left, Medium	07497561469L		
EU02055100609	Wrist Splint Black, Left, Large	07497561469L		
EU02055100709	Wrist Splint Black, Left, X-Large	07497561469L		
EU02055200309	Wrist Splint Black, Right, X-Small	07497561469L		
EU02055200409	Wrist Splint Black, Right, Small	07497561469L		



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Product Number	Label Description	Intended Purpose	Basic UDI
EU02055200509	Wrist Splint Black, Right, Medium		07497561469L
EU02055200609	Wrist Splint Black, Right, Large		07497561469L
EU02055200709	Wrist Splint Black, Right, X-Large		07497561469L
EU02510000309	Elbow Support with Vent Holes Black, X-Small	The DeRoyal® Elbow Support is intended to provide compression and support to the elbow.	07497561469L
EU02510000409	Elbow Support with Vent Holes Black, Small		07497561469L
EU02510000509	Elbow Support with Vent Holes Black, Medium		07497561469L
EU02510000609	Elbow Support with Vent Holes Black, Large		07497561469L
EU02510000709	Elbow Support with Vent Holes Black, X-Large		07497561469L
EU02510000809	Elbow Support with Vent Holes Black, XX-Large		07497561469L
EU02511000009	Tennis Elbow Strap El Temp B Black, Universal		07497561469L
EU02511000009	Tennis Elbow Support Black, Universal		07497561469L
EU02625000309	Hypercontrol Elbow Brace X-Small		The DeRoyal® Hypercontrol® Elbow Brace is intended to provide mild support and prevent excess hyperextension.
EU02625000409	Hypercontrol Elbow Brace Small	07497561469L	
EU02625000509	Hypercontrol Elbow Brace Medium	07497561469L	
EU02625000609	Hypercontrol Elbow Brace Large	07497561469L	
EU02625000709	Hypercontrol Elbow Brace X-Large	07497561469L	
EU02625000809	Hypercontrol Elbow Brace XX-Large	07497561469L	
EU02625000909	Hypercontrol Elbow Brace XXX-Large	07497561469L	
EU0325-L4	Hand Splint Air Soft, Resting	The DeRoyal® Resting Hand Splint is intended for post surgery or injury positioning, wrist drop and finger flexor tightness.	07497561469L
EU0325-L5	Hand Splint Air Soft, Resting		07497561469L
EU0325-L6	Hand Splint Air Soft, Resting		07497561469L



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Product Number	Label Description	Intended Purpose	Basic UDI
EU0325-R4	Hand Splint Air Soft, Resting		07497561469L
EU0325-R5	Hand Splint Air Soft, Resting		07497561469L
EU0325-R6	Hand Splint Air Soft, Resting		07497561469L
EU0326-L4	Hand Splint Air Soft, Stable		07497561469L
EU0326-L5	Hand Splint Air Soft, Stable		07497561469L
EU0326-L6	Hand Splint Air Soft, Stable		07497561469L
EU0326-L7	Hand Splint Air Soft, Stable		07497561469L
EU0326-R4	Hand Splint Air Soft, Stable		07497561469L
EU0326-R5	Hand Splint Air Soft, Stable		07497561469L
EU0326-R6	Hand Splint Air Soft, Stable		07497561469L
EU0326-R7	Hand Splint Air Soft, Stable		07497561469L
EU0403-L31	Hand Pucci Air Short Opponents Adult		The DeRoyal® Pucci® Air Short Opponents Inflatable Hand Orthosis is intended to provide continuous low stretch therapy to the contracted hand.
EU0403-L33	Hand Pucci Air Short Opponents Pediatric	07497561469L	
EU0403-L34	Hand Pucci Air Short Opponents Softgoods	07497561469L	
EU0403-L36	Hand Pucci Air Short Opponents Softgoods, Pediatric	07497561469L	
EU0403-R31	Hand Pucci Air Short Opponents Adult	07497561469L	
EU0403-R33	Hand Pucci Air Short Opponents Pediatric	07497561469L	
EU0403-R34	Hand Pucci Air Short Opponents Softgoods	07497561469L	
EU0403-R36	Hand Pucci Air Short Opponents Softgoods, Pediatric	07497561469L	
EU0405-L31	Hand Pucci Air-T Adult	The DeRoyal® Pucci® Air-T Inflatable Hand Orthosis is intended to provide continuous low stretch therapy to	07497561469L
EU0405-L32	Hand Pucci Air-T X-Long, Adult		07497561469L



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Product Number	Label Description	Intended Purpose	Basic UDI
EU0405-L33	Hand Pucci Air-T Pediatric	the contracted hand.	07497561469L
EU0405-L34	Hand Pucci Air-T Softgoods, Adult		07497561469L
EU0405-L35	Hand Pucci Air-T X-Long, Softgoods, Adult		07497561469L
EU0405-L36	Hand Pucci Air-T Pediatric Softgoods		07497561469L
EU0405-R31	Hand Pucci Air-T Adult		07497561469L
EU0405-R32	Hand Pucci Air-T X-Long, Adult		07497561469L
EU0405-R33	Hand Pucci Air-T Pediatric		07497561469L
EU0405-R34	Hand Pucci Air-T Softgoods, Adult		07497561469L
EU0405-R35	Hand Pucci Air-T X-Long, Softgoods, Adult		07497561469L
EU0405-R36	Hand Pucci Air-T Pediatric Softgoods		07497561469L
EU0411-L31	Hand Pucci EZE Adult		The DeRoyal® Pucci® EZE Hand Orthosis is intended to provide continuous therapy to the contracted fingers, hand and wrist.
EU0411-L33	Hand Pucci EZE Pediatric	07497561469L	
EU0411-L34	Hand Pucci EZE Softgoods	07497561469L	
EU0411-L36	Hand Pucci EZE Softgoods	07497561469L	
EU0411-R31	Hand Pucci EZE Adult	07497561469L	
EU0411-R33	Hand Pucci EZE Pediatric	07497561469L	
EU0411-R34	Hand Pucci EZE Softgoods	07497561469L	
EU0411-R36	Hand Pucci EZE Softgoods	07497561469L	
EU0413-L31	Hand Pucci Air Adult	The DeRoyal® Pucci® Air Inflatable Hand Orthosis is intended to provide continuous low stretch therapy to the contracted hand.	07497561469L
EU0413-L32	Hand Pucci Air X-Long, Adult		07497561469L
EU0413-L33	Hand Pucci Air Pediatric		07497561469L
EU0413-L34	Hand Pucci Air Softgoods		07497561469L
EU0413-L35	Hand Pucci Air Pediatric Softgoods		07497561469L
EU0413-L36	Hand Pucci Air Softgoods, Adult		07497561469L
EU0413-R31	Hand Pucci Air Adult		07497561469L
EU0413-R32	Hand Pucci Air X-Long, Adult		07497561469L



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Product Number	Label Description	Intended Purpose	Basic UDI
EU0413-R33	Hand Pucci Air Pediatric		07497561469L
EU0413-R34	Hand Pucci Air Softgoods		07497561469L
EU0413-R35	Hand Pucci Air Pediatric Softgoods		07497561469L
EU0413-R36	Hand Pucci Air X-Long, Softgoods, Adult		07497561469L
EU08010-U3	Shoulder Support - Sport XS	DeRoyal Shoulder Support is designed to provide stability and targeted compression to injured shoulders. The support immobilizes the shoulder after surgery, dislocation, sprains, and strains without restricting the arm from freedom of movement. The unique strapping system makes the brace universal for both left and right shoulders	07497561469L
EU08010-U4	Shoulder Support - Sport S		07497561469L
EU08010-U5	Shoulder Support - Sport M		07497561469L
EU08010-U6	Shoulder Support - Sport L		07497561469L
EU080100003	Sport Shoulder Support X-Small		07497561469L
EU080100004	Sport Shoulder Support Small		07497561469L
EU080100005	Sport Shoulder Support Medium		07497561469L
EU080100006	Sport Shoulder Support Large		07497561469L
EU08031-U	Wrist Support-Sport	Mild Sprains, and strains of the wrist; Tendonitis; Carpal tunnel syndrome; Overuse injuries; Tenosynovitis.	07497561469L
EU080310000	Sport Wrist Support, Pro Universal		07497561469L
EU081010003	Elbow Support, Sport w/Padding X-Small	The DeRoyal® Elbow Support is intended to provide compression and support to the elbow.	07497561469L
EU081010004	Elbow Support, Sport w/Padding Small		07497561469L
EU081010005	Elbow Support, Sport w/Padding Medium		07497561469L
EU081010006	Elbow Support, Sport w/Padding Large		07497561469L
EU081010007	Elbow Support, Sport w/Padding X-Large		07497561469L
EU081010008	Elbow Support, Sport w/Padding XX-Large		07497561469L
EU0812-U31	Pucci Finger Separator Adult	This product is intended to help position contracted or deviated fingers.	07497561469L
EU0812-U33	Pucci Finger Separator Pediatric		07497561469L



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Product Number	Label Description	Intended Purpose	Basic UDI	
EU2511-U1	Elbow Strap, Tennis Foam, D-Ring Closure	The DeRoyal® Elbow Support is intended to provide compression and support to the elbow.	07497561469L	
TX9902-02	Arm Sling With Pad	The DeRoyal Arm Sling is used for cast support injuries to the arm, wrist or hand, acromioclavicular sprains, and anterior glenohumeral dislocations	07497561469L	
TX9902-03	Arm Sling With Pad		07497561469L	
TX9902-04	Arm Sling With Pad		07497561469L	
TX9902-05	Arm Sling With Pad		07497561469L	
TX9902-06	Arm Sling With Pad		07497561469L	
EU02510-U3	Elbow Support with Vent Holes Universal, XS		The DeRoyal® Elbow Support is intended to provide compression and support to the elbow.	07497561469L
EU02510-U4	Elbow Support with Vent Holes Universal, S	07497561469L		
EU02510-U5	Elbow Support with Vent Holes Universal, M	07497561469L		
EU02510-U6	Elbow Support with Vent Holes Universal, L	07497561469L		
EU02510-U7	Elbow Support with Vent Holes Universal, XL	07497561469L		
EU02510-U8	Elbow Support with Vent Holes Universal, XXL	07497561469L		
EU02625-U3	Hypercontrol Elbow Brace Universal, XS	The DeRoyal® Hypercontrol® Elbow Brace is intended to provide mild support and prevent excess hyperextension.		07497561469L
EU02625-U4	Hypercontrol Elbow Brace Universal, S			07497561469L
EU02625-U5	Hypercontrol Elbow Brace Universal, M		07497561469L	
EU02625-U6	Hypercontrol Elbow Brace Universal, L		07497561469L	
EU02625-U7	Hypercontrol Elbow Brace Universal, XL		07497561469L	
EU02625-U8	Hypercontrol Elbow Brace Universal,		07497561469L	



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Product Number	Label Description	Intended Purpose	Basic UDI	
	XXL			
EU02625-U9	Hypercontrol Elbow Brace Universal, XXXL		07497561469L	
EU08101-U3	Elbow Supprt w/Padding - Sport X-Small	The DeRoyal® Elbow Support is intended to provide compression and support to the elbow.	07497561469L	
EU08101-U4	Elbow Supprt w/Padding - Sport Small		07497561469L	
EU08101-U5	Elbow Supprt w/Padding - Sport Medium		07497561469L	
EU08101-U6	Elbow Supprt w/Padding - Sport Large		07497561469L	
EU08101-U7	Elbow Supprt w/Padding - Sport X-Large		07497561469L	
EU08101-U8	Elbow Supprt w/Padding - Sport XX-Large		07497561469L	
EU00325100609	Hand Splint Air Soft Resting Left, Small		The DeRoyal® Resting Hand Splint is intended for post surgery or injury positioning, wrist drop and finger flexor tightness	07497561469L
EU00325200609	Hand Splint Air Soft Resting Left, Medium			07497561469L
EU00325100509	Hand Splint Air Soft Resting Left, Large	07497561469L		
EU00325200509	Hand Splint Air Soft Resting Right, Small	07497561469L		
EU00325100409	Hand Splint Air Soft Resting Right, Medium	07497561469L		
EU00325200409	Hand Splint Air Soft Resting Right, Large	07497561469L		
804	Finger Buddy Straps	The DeRoyal® Buddy Strap is intended for finger fractures, ligament injuries or injuries requiring buddy tape.		07497561469L
140-0200-00	mBrace Wrist Support with Foam	The mBrace can be used for extending the wrist to 40	07497561469L	



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Product Number	Label Description	Intended Purpose	Basic UDI
	Pad	degrees when inserting lines or catheters in the radial artery or other arteries in the wrist. A foam pad is included for optionally padding the hand or increasing the angle of extension.	
4220B	Inflatable Elbow Orthosis	The DeRoyal® Pucci® Inflatable Elbow Orthosis is intended to provide continuous low stretch therapy to the contracted elbow.	07497561469L
4220C	Inflatable Elbow Orthosis		07497561469L
EU02010200403	Wrist Basic, Short Beige, Right, Small	Mild sprains and strains of the wrist; Tendonitis, Carpal tunnel syndrome; Overuse injuries; Tenosynovitis	07497561469L
EU02010200503	Wrist Basic, Short Beige, Right, Medium		07497561469L
EU02030200409	Wrist Splint, Short Black, Right, Small		07497561469L
EU02030200509	Wrist Splint, Short Black, Right, Medium		07497561469L
EU02040200803	Wrist Splint, Optimal, Short Beige, Right, XX-Large		07497561469L


DER.DOC.146 MDR - Upper Extremity Supports and Braces

Final Audit Report

2021-10-28

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