

Declaration of Conformity                      Class I Medical Device

Products

Upper Extremity Orthosis

Are in Conformity with the following Standards

BS EN ISO 14971:21012 Application of Risk Management to Medical Devices.

prEN 15223-1-2016 Terminology, Symbols and Information provided with Medical Devices; Graphical Symbols for use in Labeling of Medical Devices.

prEN 1041 Terminology, Symbols and Information supplied by the manufacturer with Medical Devices.

I hereby declare that products specified above are CE Marked being classified as Class I devices (Annex IX, rule 1) and conform to the requirements of the Council Directives 93/42/EEC, as amended by 2007/47/EC. The Conformity Assessment Procedure for CE marking: Annex VII of the MDD.

Bokholt Hanredder                      11.01.2019

Bestätigt durch :

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## List of Devices

Group Name	Device Name	Model / Part No.	Risk Class / Rule	First Date of CE Compliance
Upper Extremity Orthosis	Knuckle Bender XS	0474-01	Class I/Rule 1	01.02.19
Upper Extremity Orthosis	Knuckle Bender S	0474-02	Class I/Rule 1	01.02.19
Upper Extremity Orthosis	Knuckle Bender M	0474-03	Class I/Rule 1	01.02.19
Upper Extremity Orthosis	Knuckle Bender L	0474-04	Class I/Rule 1	01.02.19
Upper Extremity Orthosis	Knuckle Bender XL	0474-05	Class I/Rule 1	01.02.19
Upper Extremity Orthosis	Knuckle Bender w. Segment XS	0475-01	Class I/Rule 1	01.02.19
Upper Extremity Orthosis	Knuckle Bender w. Segment S	0475-02	Class I/Rule 1	01.02.19
Upper Extremity Orthosis	Knuckle Bender w. Segment M	0475-03	Class I/Rule 1	01.02.19
Upper Extremity Orthosis	Knuckle Bender w. Segment L	0475-04	Class I/Rule 1	01.02.19
Upper Extremity Orthosis	Knuckle Bender w. Segment XL	0475-05	Class I/Rule 1	01.02.19
Upper Extremity Orthosis	Finger Extension Splint XS	4012-01	Class I/Rule 1	01.02.19
Upper Extremity Orthosis	Finger Extension Splint S	4012-02	Class I/Rule 1	01.02.19
Upper Extremity Orthosis	Finger Extension Splint M	4012-03	Class I/Rule 1	01.02.19
Upper Extremity Orthosis	Finger Extension Splint L	4012-04	Class I/Rule 1	01.02.19
Upper Extremity Orthosis	Finger Extension Splint XL	4012-05	Class I/Rule 1	01.02.19
Upper Extremity Orthosis	Spring Wire Safety Pin XS	0472-01	Class I/Rule 1	01.02.19
Upper Extremity Orthosis	Spring Wire Safety Pin S	0472-02	Class I/Rule 1	01.02.19
Upper Extremity Orthosis	Spring Wire Safety Pin M	0472-03	Class I/Rule 1	01.02.19
Upper Extremity Orthosis	Spring Wire Safety Pin L	0472-04	Class I/Rule 1	01.02.19
Upper Extremity Orthosis	Spring Wire Safety Pin XL	0472-05	Class I/Rule 1	01.02.19
Upper Extremity Orthosis	Mini Safety Pin 1	0471-01	Class I/Rule 1	01.02.19
Upper Extremity Orthosis	Mini Safety Pin 2	0471-02	Class I/Rule 1	01.02.19
Upper Extremity Orthosis	Mini Safety Pin 3	0471-03	Class I/Rule 1	01.02.19
Upper Extremity Orthosis	Mini Safety Pin 4	0471-04	Class I/Rule 1	01.02.19

Upper Extremity Orthosis	Modified Safety Pin XS	6308-01	Class I/Rule 1	01.02.19
Upper Extremity Orthosis	Modified Safety Pin S	6308-02	Class I/Rule 1	01.02.19
Upper Extremity Orthosis	Modified Safety Pin M	6308-03	Class I/Rule 1	01.02.19
Upper Extremity Orthosis	Modified Safety Pin L	6308-04	Class I/Rule 1	01.02.19
Upper Extremity Orthosis	Modified Safety Pin XL	6308-05	Class I/Rule 1	01.02.19
Upper Extremity Orthosis	Mini Modified Safey Pin Size 1	6307-01	Class I/Rule 1	01.02.19
Upper Extremity Orthosis	Mini Modified Safey Pin Size 2	6307-02	Class I/Rule 1	01.02.19
Upper Extremity Orthosis	Mini Modified Safey Pin Size 3	6307-03	Class I/Rule 1	01.02.19
Upper Extremity Orthosis	Mini Modified Safey Pin Size 4	6307-04	Class I/Rule 1	01.02.19
Upper Extremity Orthosis	Composite Spring S	0476-01	Class I/Rule 1	01.02.19
Upper Extremity Orthosis	Composite Spring M	0476-02	Class I/Rule 1	01.02.19
Upper Extremity Orthosis	Composite Spring L	0476-03	Class I/Rule 1	01.02.19
Upper Extremity Orthosis	Finger Knuckle Bender XS	6312-01	Class I/Rule 1	01.02.19
Upper Extremity Orthosis	Finger Knuckle Bender S	6312-02	Class I/Rule 1	01.02.19
Upper Extremity Orthosis	Finger Knuckle Bender M	6312-03	Class I/Rule 1	01.02.19
Upper Extremity Orthosis	Finger Knuckle Bender L	6312-04	Class I/Rule 1	01.02.19
Upper Extremity Orthosis	Finger Knuckle Bender XL	6312-05	Class I/Rule 1	01.02.19
Upper Extremity Orthosis	Reverse Finger Knuckle Bender XS	6309-01	Class I/Rule 1	01.02.19
Upper Extremity Orthosis	Reverse Finger Knuckle Bender S	6309-02	Class I/Rule 1	01.02.19
Upper Extremity Orthosis	Reverse Finger Knuckle Bender M	6309-03	Class I/Rule 1	01.02.19
Upper Extremity Orthosis	Reverse Finger Knuckle Bender L	6309-04	Class I/Rule 1	01.02.19
Upper Extremity Orthosis	Reverse Finger Knuckle Bender XL	6309-05	Class I/Rule 1	01.02.19
Upper Extremity Orthosis	PIP Extension XS	6310-01	Class I/Rule 1	01.02.19
Upper Extremity Orthosis	PIP Extension S	6310-02	Class I/Rule 1	01.02.19
Upper Extremity Orthosis	PIP Extension M	6310-03	Class I/Rule 1	01.02.19

Upper Extremity Orthosis	PIP Exension L	6310-04	Class I/Rule 1	01.02.19
Upper Extremity Orthosis	PIP Exension XL	6310-05	Class I/Rule 1	01.02.19
Upper Extremity Orthosis	PIP Spring Extension S	6311-01	Class I/Rule 1	01.02.19
Upper Extremity Orthosis	PIP Spring Extension M	6311-02	Class I/Rule 1	01.02.19
Upper Extremity Orthosis	PIP Spring Extension L	6311-03	Class I/Rule 1	01.02.19
Upper Extremity Orthosis	PIP Spring Extension XL	6311-04	Class I/Rule 1	01.02.19