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Valentine International Limited

Declaration of Conformity

Manufacturer: Valentine International Ltd. 221 Hsichih District, New Taipei City Taiwan R.O.C.

Authorized Representative: Y. Sung Handelsvertretung Duesselthaler Str. 24 40211 Duesseldorf, Germany SRN: DE-AR-000005142

Products:

Valentine	Servoprax item #	Description	Intended Purpose	UDI#
item #				
10022	M1 40A	Push-Button Aluminum Crutches	A mobility aid in the form of a waist-high framework with handgrips and the four or three legs designed to provide a stable support to a person with a disability, a geriatric or an infirm person when standing or ambulating; it may also be used during rehabilitation. It is constructed of lightweight metaplastic, and rowher materials in the shape of a mobile support structure which the user holds as they walk. It may be height-adjustable and some types may include a seat on which the user can rest.	471987970122
10422	M1 344001W	Deluxe Tub Bar	A grab bar intended to provide a supportive hand-hold for a person with a disability when raising or lowering themselves or changing their body position while bathing in a bath or bathing facility. It will typically be affixed to or around the bath.	4719879709858
17002	M1 17002	Deluxe Post-Op Shoe, Small Female	A post op shoe used to protect the foot and toes after an injury or surgery.	4719879707632
17003	M1 17003	Deluxe Post-Op Shoe, Medium Female	A post op shoe used to protect the foot and toes after an injury or surgery.	4719879707649
17004	M1 17004	Deluxe Post-Op Shoe, Large, Female	A post op shoe used to protect the foot and toes after an injury or surgery.	4719879707656
17012	M1 17012	Deluxe Post-Op Shoe, Small Male	A post op shoe used to protect the foot and toes after an injury or surgery.	4719879707663
17013	M1 17013	Deluxe Post-Op Shoe, Medium, Male	A post op shoe used to protect the foot and toes after an injury or surgery.	4719879707670
17014	M1 17014	Deluxe Post-Op Shoe,Large , Male	A post op shoe used to protect the foot and toes after an injury or surgery.	4719879707687
41101	M1 57050	Stax Finger Splint	Finger Splints are used to keep these vulnerable extremities in place while you heal form a finger sprain or break.	4719879704037
41102	M1 57051	Stax Finger Splint	Finger Splints are used to keep these vulnerable extremities in place while you heal form a finger sprain or break.	4719879704044
41103	M1 57052	Stax Finger Splint	Finger Splints are used to keep these vulnerable extremities in place while you heal form a finger sprain or break.	4719879704051
41104	M1 57053	Stax Finger Splint	Finger Splints are used to keep these vulnerable extremities in place while you heal form a finger sprain or break.	4719879704068
41105	M1 57054	Stax Finger Splint	Finger Splints are used to keep these vulnerable extremities in place while you heal form a finger sprain or break.	4719879704075
41105,5	M1 57055	Stax Finger Splint	Finger Splints are used to keep these vulnerable extremities in place while you heal form a finger sprain or break.	4719879704082
41106	M1 57056	Stax Finger Splint	Finger Splints are used to keep these vulnerable extremities in place while you heal form a finger sprain or break.	4719879704099
41107	M1 57057	Stax Finger Splint	Finger Splints are used to keep these vulnerable extremities in place while you heal form a finger sprain or break.	4719879704105
10535/A	M1 B31	Aluminum Toilet Safety Frame	Toilet rail provide users with added stability while lowering onto and rising from the toilet.	4719879707281
10188SL	M1 204030	Reciprocal Folding Walker, Adult	Nowheeled mobility aid in the form of a waist-high framework with handgrips and designed to provide a stable support to a person with a disability, a geriatric or an infirm person when standing or ambulating; it may also be used during rehabilitation. It is constructed of lightweight metal, plastic, and rubber materials in the shape of a mobile support structure which the user holds and pushes in front of them as they walk	4719879709827
10180SL	M1 204081BR	Deluxe Folding Walker, Adult,	Nowheeled mobility aid in the form of a waist-high framework with handgrips and designed to provide a stable support to a person with a disability, a geriatric or an infirm person when standing or ambulating; it may also be used during rehabilitation. It is constructed of lightweight metal, plastic, and rubber materials in the shape of a mobile support structure which the user holds and pushes in front of them as they walk	4719879701418

We hereby declare on our own responsibility that the products specified above meets all provisions of the Medical Device Regulation (EU) 2017/745, which apply to them. $\label{eq:decomposition} \mbox{Directive classification according to annex VIII: class I, rule 1}$

Conformity assessment procedure according to annex IV/V of Regulation (EU) 2017/745.

Authorized signature:

Jan 10 2022

July 25