



# EU Declaration of Conformity

Manufacturer	R82 A/S Parallelsvej 3 DK-8751 Gedved Denmark Phone: +45 7965 5888 <a href="http://www.etac.com">www.etac.com</a>
SRN	DK-MF-000000772
Statement	This declaration of conformity is issued under the sole responsibility of the manufacturer. The device(s) covered by this declaration of conformity is/are in conformity with EU Regulation 2017/745 on medical devices.
Basic UDI-DI	570729218100036
EMDN	NA
Intended Purpose	Accessories for seating, standing, walking and toilet & bath devices for persons with disabilities.
Device name(s)	See below list
Risk class of the device	Class I, Rule 1
Harmonized/Established Standards	Separate list available upon request
Place	Gedved, Denmark
Date of issue	2024-12-06
Name and function	Claus Riis – QA & RA Manager



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Signature, on behalf of manufacturer

Category	Medical Device name
Arm Supports	Arm prompts Arm rest extension Arm rests Arm rests, incl. side plates and tray holders Arm rest for tray Forearm support Grip bar in arm rests Hand bar Handle knobs Handles Infant arm support kit incl. Cover Infant hip/arm support incl. Cover Padded forearm positioner Rod for arm rest Upper arm support
Back Supports	Back and side support Back extension Back reinforcement kit Back sides with cushions Back support Back wedge Back width extensions Cover plate Cross bar for mounting back support Fixed rod for back Foam back plate Kit for dynamic back rest with recline Lower back extension Rod for back User operated back adjustment
Head Supports	Connection system for head support Head and back support Head rest fitting Head support Head support plate Mounting for head support Pads for head support Top plate
Trays And Activity Centres	Activity centre Play box Toybar Toybar for tray Tray

Leg And Foot Supports	<p>Additional locking mechanism for foot plate</p> <p>Angling of lower leg</p> <p>Ankle prompts</p> <p>Bar/rod for foot support</p> <p>Calf support + strap + cover</p> <p>Foot plate</p> <p>Foot rest</p> <p>Foot support</p> <p>Heel band/strap</p> <p>Knee support</p> <p>Leg pad</p> <p>Leg protection</p> <p>Leg rest</p> <p>Leg separator</p> <p>Leg support</p> <p>Mounting for foot support</p> <p>Sandals</p> <p>Width extension for multi-adjustable foot support</p>
Abduction And Adduction	<p>Adductors</p> <p>Knee abduction pommel</p> <p>Pommel</p> <p>Strap for pommel</p>
Cushions And Covers	<p>Arm rest covers</p> <p>Back rest cushion</p> <p>Back extension cushion</p> <p>Cover</p> <p>Cover for infant seat cushion</p> <p>Covers for knobs on side supports</p> <p>Extra cover for calf support</p> <p>Extra padding</p> <p>Girth for seat cushion without abduction</p> <p>Incontinence cover</p> <p>Infant cushion</p> <p>Infant arm support cover</p> <p>Infant back cushion without cover</p> <p>Infant back plate without cushion or cover</p> <p>Infant seat cushion without cover</p> <p>Infant leg support plate without cover</p> <p>Inlay seat with wider sides</p> <p>Padding for foot support</p> <p>Padding for tray with bowl</p> <p>Pommel padding</p> <p>Seat cushion</p> <p>Seat infill</p> <p>Upholstery</p> <p>Upholstery for shoulder support</p> <p>Wedge for infant seating</p> <p>Cover for back sides</p>

Postural Supports	Abdominal support / pad
	Chest support
	Distance piece
	Hip support
	Lumbar support
	Pads for head/lateral support
	Pelvic support
	Quick locks for side supports
	Sacrum support
	Seat wedges
	Shoulder support
	Side support / sides
	Straps for side supports
	Trunk support
	Wedges
	Wedges for shaping seat and back
	Wedges width reduction kit
Belts Straps And Vests	5 point belt (transportation)
	Belts
	Calf support strap
	Chest strap
	Cross straps
	Fix lock fittings
	Fix locks
	Heel band
	Storage strap
	Torso belt
	Torso strap
	Vests
Seating	Flip down seat
	Seat
	Seat depth reduction
	Seat extension
	Seat height extension
	Sling seat
Anti Tippers	Anti-tip
Attachments For Medical Devices	Oxygen bottle holder
	Vent tray
Bags And Baskets	Bunting bag
	Net for Manatee
	Rucksack / backpack
	Shopping basket
	Storage pouch

Brakes	Central brake kit Hand brakes
Castors	Castors Castors with directional stabilizers Directional stabilizer
Fixations And Brackets	Daily adjustment kit, knee support Displacement kit Fixture for connecting PF to HL outdoor Support rod kit
Gas Springs	Extra gas spring Non-dynamic gas spring
Handles And Push Braces	Grip bar in frame Grip handle for tray Height adjustable push brace kit Helper's handles / guide bar / Attendants handle Push brace
Mounting Kits	Adapter/interface Conversion kit for rebuilding manual Caribou into telescopic Extension for centre bar Foot pedal kit Wall mounting x:panda kit
Outdoor Use	Canopy Folding top Rain cover/rain cape
Power Supply	Charger Power kit
Rocker	Rocker
Storage And Transportation	Transport fitting Storage bag
Tilt And Recline	Recline add-on
Wheels	Camber kit Directional locking mechanism Front wheels Kit for push rim displacement Mud guards Rear wheels Spoke protectors

Frames	Frame for Manatee
	Potty frame
	Floor Frame
Bath Accessories	Extension hose
	Suction cups
Toilet Accessories	Commode pan
	Fitting for toilet mounting
	Lid for commode pan
	Potty ring
	Splash guard