



EU Declaration of Conformity

Manufacturer	R82 A/S Parallevej 3 DK-8751 Gedved Denmark Phone: +45 7965 5888 www.etac.com
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	2024-12-10
Name and function	Claus Riis – QA & RA Manager



Signature, on behalf of manufacturer

Category	Medical Device name	
Arm Supports	Arm prompts	
	Arm rest extension	
	Arm rests/supports (fixed, swingaway, double rod)	
	Arm rests, incl. side plates and tray holders	
	Arm rest for tray	
	Arm support	
	Forearm support	
	Grip bar in arm rests	
	Hand bar	
	Handle knobs	
	Handles	
	Kit from fixed to swingaway armrest	
	Infant arm support kit incl. Cover	
	Infant hip/arm support incl. Cover	
	Padded forearm positioner	
	Rod for arm rest	
	Upper arm support (fixed, adjustable)	
	Back Supports	Back (upper, lower)
		Back and side support
		Back extension
Back reinforcement kit		
Back sides with cushions		
Back support		
Back support adjustable		
Back support step 1 to 2 kit (seat, back)		
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		
Short to long back		
Surrounding support		
User operated back adjustment		

Head Supports	<ul style="list-style-type: none"> Connection system for head support Head and back support Head rest fitting Head support (including two-parted, sculpted, anatomic, curved) Head support plate Mounting for head support Pads for head support Top plate
Trays And Activity Centres	<ul style="list-style-type: none"> Activity centre Play box Soft tray Toybar Toybar for tray Tray
Leg And Foot Supports	<ul style="list-style-type: none"> Additional locking mechanism for foot plate Angling of lower leg Angle adjustable foot support Ankle prompts Ankle Straps Calf support + strap + cover Foot box kit Foot plate/Foot rest/Foot support Foot strap Heel band/strap Knee supports (including inner and outer) Leg pad Leg protection Leg rest Leg separator Leg support Mounting/bar/rod for foot support (single, double) Mounting for foot plate for higher fitting Multi adjustable foot support Multi adjustable foot support extended holders Padded foot support Parted foot support Sandals (clips, bar) Strap for foot box/plate Width extension for multi-adjustable foot support
Abduction And Adduction	<ul style="list-style-type: none"> Adductors Knee abduction pommel Pommel (including with quick release) Strap for pommel

Cushions And Covers

Arm rest covers
Back cushion (back rest, upper, lower, extension, contoured)
Cover
Cover for back side
Cover for infant seat cushion
Covers for knobs on side supports
Cover for spacer block cushion
Extra cover for calf support
Extra padding
Girth for seat cushion without abduction
Head support cushion
Hip support cover
Incontinence cover
Infant cushion (including Chilla, x:panda shape, x:panda shape TS)
Infant arm support cover
Infant back cushion without cover
Infant back plate without cushion or cover
Infant seat cushion without cover
Infant side support belt cover
Infant leg support plate without cover
Inlay seat with wider sides
Padding for foot support
Padding for foot box kit
Padding for foot plate rod
Padding for tray
Pommel padding
Seat cushion (including standard, contoured)
Seat infill
Spacer block cushion
Upholstery
Upholstery for shoulder support
Wedge for infant seating

Postural Supports

Abdominal support / pad
 Chest support
 Distance piece
 Hip support (adjustable, fixed)
 Infant side support belt
 Lumbar support/wedge
 Pads for head/lateral support
 Pelvic/pelvis support
 Pelvis support with sides
 Quick locks/snap lock for side supports
 Sacrum support
 Seat wedges/wedges for seat pit
 Shoulder support
 Side supports (fixed, swingaway, angle adjustable)
 Sides
 Spacer block
 Spacer block holder
 Straps for side supports
 Therapy kit tubes
 Trunk support
 Wedges
 Wedges for shaping seat and back
 Wedges width reduction kit

Belts Straps And Vests

Abdominal support belt for back support
 5 point belt (transportation)
 Belts
 Calf support strap
 Chest belt
 Chest strap
 Combination harness
 Cross straps
 Fix locks
 H-belt
 Hand wrist cuff
 Hip belt (Y-hip, upholstered, trochanter)
 Heel band
 Lap/chest strap
 Lateral strap
 Pelvis belt
 Pelvis harness
 Shoulder strap
 Storage strap
 Sternum belt
 Torso belt
 Torso strap
 Thorax/pelvis strap
 Vests (cross, torso, net)

Seating	<ul style="list-style-type: none"> Chilla seat (size 1 and 2) Flip down seat Seat Seat depth reduction Seat extension Seat height extension Sling seat Sling seat lightweight
Anti Tippers	<ul style="list-style-type: none"> Anti-tip (indoor, outdoor, fixed, swingaway)
Attachments For Medical Devices	<ul style="list-style-type: none"> Oxygen bottle holder IV-pole Vent tray/Medical tray
Bags And Baskets	<ul style="list-style-type: none"> Bag Bunting bag Net for Manatee Rucksack / backpack Shopping basket Storage pouch
Brakes	<ul style="list-style-type: none"> Central brake kit (hand/foot operated) Hand brakes/foot brake Retro fit kit for brakes Running brake/decelerating brake Parking brake
Castors	<ul style="list-style-type: none"> Castors Castors with directional stabilizers Directional stabilizer Wheels

Fixations And Brackets	<ul style="list-style-type: none"> Attachment for grip bar and tray Brackets Bracket/mounting for Canopy and folding top Bracket for communication aid Brackets for fix locks (higher, wider, additional fix locks) Bracket for head support Daily adjustment kit (knee support, arm support, back, head support) Displacement kit Fixture for connecting PF to HL outdoor Head support bracket for i2i Hinge cap Holders for mounting Holders for handbrakes Holder for remote control (for arm support, back) Lock for height adjustment Support rod kit
Gas Springs	<ul style="list-style-type: none"> Extra gas spring Non-dynamic gas spring
Handles And Push Braces	<ul style="list-style-type: none"> Angle/height adjustable grip bar Grip bar (for frame, armrest, tray, handle) Grip handle for tray Height adjustable push brace kit Height lever kit for retro fitting Helper's handles / guide bar / Attendants handle Mounting kit push brace on size 3 Push brace/handle (fixed, angle adjustable)
Mounting Kits	<ul style="list-style-type: none"> Adapter/interface Adapter for seat mount Conversion kit for rebuilding manual Caribou into telescopic Crocodile starter kit Extension for centre bar Foot pedal kit Rebuild mounting kit (infant, simple, advanced, seat plate) Wall mounting x:panda kit
Outdoor Use	<ul style="list-style-type: none"> Canopy (premium, standard) Folding top Rain cover/rain cape Termo bag
Power Supply	<ul style="list-style-type: none"> Charger Power kit (including gas to power)
Rocker	<ul style="list-style-type: none"> Rocker

Storage And Transportation	Transport fitting Threshold assistance Storage bag
Tilt And Recline	Recline add-on Dynamic back recline module Tilt lever kit for retro fitting on push brace
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