



EU Declaration of Conformity

Manufacturer	R82 A/S Parallelvej 3 DK-8751 Gedved Phone: +45 79655888 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	2024.03.20
Name and function	Dianna Hessellund Jensen – Director QA/RA

Signature, on behalf of R82 A/S



Category Arm Supports

Back Supports

Head Supports

Trays And Activity Centres

Leg And Foot Supports

Medical Device name Arm prompts Arm rest extension Arm rests Arm rests, incl. side plates and tray holders Arm rest covers Arm rest for tray Forearm support Grip bar in arm rests Hand bar Handle knobs Handles Padded forearm positioner Rod for arm rest Upper arm support Back and side support Back extension Back extension cushion 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 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 Activity centre Play box Toybar Toybar for tray Tray Additional locking mechanism for foot plate Angling of lower leg Ankle prompts Bar/rod for foot support Calf support + strap + cover Foot plate Foot rest Foot support Heel band/strap Knee support Leg pad Leg protection Leg rest Leg separator Leg support Mounting for foot support Sandals

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Width extension for multi-adjustable foot support

Abduction And Adduction	Adductors Knee abduction pommel Pommel Strap
Cushions And Covers	for pommel Arm rest covers Back rest cushion Cover Covers for knobs on side supports Extra cover for calf support Extra padding Girth for seat cushion without abduction Incontinence cover Inlay seat with wider sides Padding for foot support Padding for tray with bowl Pommel padding Seat cushion Seat infill Upholstery Upholstery for shoulder support
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
Belts Straps And Vests	Shoulder support Side support / sides Straps for side supports Trunk support Wedges Wedges for shaping seat and back Wedges width reduction kit 5 point belt (transportation) Belts Calf support strap Chest strap Chest straps Fix lock fittings Fix locks Heel band
Seating	Storage strap Torso belt Torso strap Vests Flip down seat Seat Seat depth reduction Seat extension Seat height extension
Anti Tippers Attachments For Medical Devices	Sling seat Anti-tip Oxygen bottle holder

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Bags And Baskets Bunting bag Net for Manatee Shopping basket Storage pouch Central brake kit Hand brakes Castors **Fixations And Brackets** Displacement kit Support rod kit Gas Springs Extra gas spring Handles And Push Braces Grip bar in frame handle Push brace Mounting Kits Adapter/interface Foot pedal kit Outdoor Use Canopy Folding top Power Supply Charger Power kit Rocker Storage And Transportation Tilt And Recline Recline add-on Camber kit Front wheels Mud guards Rear wheels Spoke protectors Potty frame Floor frame Bath Accessories Extension hose Suction cups **Toilet Accessories**

Brakes

Castors

Rocker

Wheels

Frames

Vent tray

Rucksack / backpack Castors with directional stabilizers Directional stabilizer Daily adjustment kit, knee support Fixture for connecting PF to HL outdoor Non-dynamic gas spring Grip handle for tray Height adjustable push brace kit Helper's handles / guide bar / Attendants Conversion kit for rebuilding manual Caribou into telescopic Extension for centre bar Wall mounting x:panda kit Rain cover/rain cape Transport fitting Storage bag Directional locking mechanism Kit for push rim displacement Frame for Manatee Commode pan Fitting for toilet mounting Lid for commode pan Potty ring Splash guard

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