



EU DECLARATION OF CONFORMITY

Manufacturer R82 A/S

Parallelvej 3

DK-8751 Gedved

Denmark

SRN DK-MF-000000772

Statement This EU declaration of conformity is issued under the sole responsibility of the

manufacturer

The device(s) covered by present declaration is/are in conformity with EU

Regulation 2017/745 on medical devices

Basic UDI-DI 570729218100036

Intended purpose Accessories for seating, standing, walking and toilet & bath devices for persons

with disabilities

Product / device name See below list

Risk class of the device Class I

Place Gedved, Denmark

Date of issue 26. April 2021

Name and function Ulla Lange, Director of QA and Regulatory Affairs

Signature, on behalf of R82 A/S





Category Medical Device name

Arm Supports 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 Supports 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

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 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

Width extension for multi-adjustable foot support





Abduction And Adduction Adductors

Knee abduction pommel

Pommel

Strap for pommel

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
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

Oxygen bottle holder

Devices

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

Assistive Frames Frame for Manatee

Potty frame

Bath Accessories Extension hose

Suction cups

Toilet Accessories Commode pan

Fitting for toilet mounting Lid for commode pan

Potty ring Splash guard