



# UK DECLARATION OF CONFORMITY

In accordance with UK Government Guidance

<b>Manufacturer</b>	R82 A/S Parallelvej 3 DK-8751 Gedved Denmark Phone: +45 7965 5888 <a href="http://www.etac.com">www.etac.com</a>	<b>UK Responsible Person</b>	Etac Ltd Unit 60, Hartlebury Trading Estate, Hartlebury, Kidderminster, DY10 4JD Email <a href="mailto:enquiries.uk@etac.com">enquiries.uk@etac.com</a> Web <a href="http://www.etac.com/uk">www.etac.com/uk</a> Phone +44 (0)121 561 2222
<b>Statement</b>	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 UK MDR 2002 (Medical Device Regulations 2002)		
<b>Basic UDI-DI</b>	570729218100036		
<b>GMDN</b>	NA		
<b>Intended purpose</b>	Accessories for seating, standing, walking and toilet & bath devices for persons with disabilities.		
<b>Device name(s)</b>	See below list		
<b>Risk class of the device</b>	Class I, rule 1		
<b>Harmonized/Established Standards</b>	Separate list available upon request		
<b>Place</b>	Gedved, Denmark		
<b>Date of issue</b>	2024-12-12		
<b>Name and function</b>	Claus Riis – QA & RA Manager		

Signature, on behalf of manufacturer

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

Abduction And Adduction	<p>Adductors Knee abduction pommel Pommel (including with quick release) Strap for pommel</p>
Cushions And Covers	<p>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</p>

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	<p>Abdominal support belt for back support</p> <p>5 point belt (transportation)</p> <p>Belts</p> <p>Calf support strap</p> <p>Chest belt</p> <p>Chest strap</p> <p>Combination harness</p> <p>Cross straps</p> <p>Fix locks</p> <p>H-belt</p> <p>Hand wrist cuff</p> <p>Hip belt (Y-hip, upholstered, trochanter)</p> <p>Heel band</p> <p>Lap/chest strap</p> <p>Lateral strap</p> <p>Pelvis belt</p> <p>Pelvis harness</p> <p>Shoulder strap</p> <p>Storage strap</p> <p>Sternum belt</p> <p>Torso belt</p> <p>Torso strap</p> <p>Thorax/pelvis strap</p> <p>Vests (cross, torso, net)</p>
Seating	<p>Chilla seat (size 1 and 2)</p> <p>Flip down seat</p> <p>Seat</p> <p>Seat depth reduction</p> <p>Seat extension</p> <p>Seat height extension</p> <p>Sling seat</p> <p>Sling seat lightweight</p>
Anti Tippers	<p>Anti-tip (indoor, outdoor, fixed, swingaway)</p>
Attachments For Medical Devices	<p>Oxygen bottle holder</p> <p>IV-pole</p> <p>Vent tray/Medical tray</p>

Bags And Baskets	<ul style="list-style-type: none"> <li>Bag</li> <li>Bunting bag</li> <li>Net for Manatee</li> <li>Rucksack / backpack</li> <li>Shopping basket</li> <li>Storage pouch</li> </ul>
Brakes	<ul style="list-style-type: none"> <li>Central brake kit (hand/foot operated)</li> <li>Hand brakes/foot brake</li> <li>Retro fit kit for brakes</li> <li>Running brake/decelerating brake</li> <li>Parking brake</li> </ul>
Castors	<ul style="list-style-type: none"> <li>Castors</li> <li>Castors with directional stabilizers</li> <li>Directional stabilizer</li> <li>Wheels</li> </ul>
Fixations And Brackets	<ul style="list-style-type: none"> <li>Attachment for grip bar and tray</li> <li>Brackets</li> <li>Bracket/mounting for Canopy and folding top</li> <li>Bracket for communication aid</li> <li>Brackets for fix locks (higher, wider, additional fix locks)</li> <li>Bracket for head support</li> <li>Daily adjustment kit (knee support, arm support, back, head support)</li> <li>Displacement kit</li> <li>Fixture for connecting PF to HL outdoor</li> <li>Head support bracket for i2i</li> <li>Hinge cap</li> <li> Holders for mounting</li> <li> Holders for handbrakes</li> <li> Holder for remote control (for arm support, back)</li> <li> Lock for height adjustment</li> <li> Support rod kit</li> </ul>
Gas Springs	<ul style="list-style-type: none"> <li>Extra gas spring</li> <li>Non-dynamic gas spring</li> </ul>



Handles And Push Braces	<ul style="list-style-type: none"> <li>Angle/height adjustable grip bar</li> <li>Grip bar (for frame, armrest, tray, handle)</li> <li>Grip handle for tray</li> <li>Height adjustable push brace kit</li> <li>Height lever kit for retro fitting</li> <li>Helper's handles / guide bar / Attendants handle</li> <li>Mounting kit push brace on size 3</li> <li>Push brace/handle (fixed, angle adjustable)</li> </ul>
Mounting Kits	<ul style="list-style-type: none"> <li>Adapter/interface</li> <li>Adapter for seat mount</li> <li>Conversion kit for rebuilding manual Caribou into telescopic</li> <li>Crocodile starter kit</li> <li>Extension for centre bar</li> <li>Foot pedal kit</li> <li>Rebuild mounting kit (infant, simple, advanced, seat plate)</li> <li>Wall mounting</li> <li>x:panda kit</li> </ul>
Outdoor Use	<ul style="list-style-type: none"> <li>Canopy (premium, standard)</li> <li>Folding top</li> <li>Rain cover/rain cape</li> <li>Termo bag</li> </ul>
Power Supply	<ul style="list-style-type: none"> <li>Charger</li> <li>Power kit (including gas to power)</li> </ul>
Rocker	<ul style="list-style-type: none"> <li>Rocker</li> </ul>
Storage And Transportation	<ul style="list-style-type: none"> <li>Transport fitting</li> <li>Threshold assistance</li> <li>Storage bag</li> </ul>
Tilt And Recline	<ul style="list-style-type: none"> <li>Recline add-on</li> <li>Dynamic back recline module</li> <li>Tilt lever kit for retro fitting on push brace</li> </ul>



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