

EU DECLARATION OF CONFORMITY

We declare that the products listed in the attached Schedule I conform to the EU Medical Device Directive 93/42/EEC and EN12182 and therefore bear the CE mark. Rifton's quality system conforms to ISO 13485:2003 and Title 21 of the US Code of Federal Regulations, Section 820. Rifton's risk analysis program conforms to ISO 14971.

Manufacturer:

Rifton Equipment
2032 Rt 213
Rifton NY 1247
USA

Representative in EU:

Community Playthings (Ref # CA 005888)
Brightling Road
Robertsbridge, TN32 5DR
United Kingdom

Products:

See Attached: Schedule I

Conformity Assessment

Mechanical Safety Requirements:

- ✓ Must not break or distort in normal use to result in injury. (EN12182 part 16)
- ✓ Must not have exposed protrusions or sharp edges which could cause injury. (EN12182 part 18)
- ✓ Minimize risk of injury from pinch points. (EN12182 part 12,14)
- ✓ Items which a child can get into must have a means of escape from the inside. (EN12182 part 13)
- ✓ Items with heating elements must not have any accessible surfaces that could burn either directly or by gases etc. escaping. (EN12182 part 10)
- ✓ Product must not cause injury or undue discomfort to the user under normal, foreseeable circumstances, esp. products for weight-bearing or positioning. (EN12182 part 21)
- ✓ Stability must pass EN12182 part 4.2.

Chemical Properties:

- ✓ Must not pose health risks by ingestion, inhalation, contact with skin, mucous tissue or eyes.
- ✓ Must eliminate the risk of toxic metals entering the blood by ingestion.
- ✓ Must not contain dangerous substances.

Electrical Properties:

- ✓ Voltage must not exceed 24 volts.
- ✓ Parts of items which are liable to come into contact with a source of electricity must be insulated and mechanically protected to avoid shock. (EN12182 part 8.1)
- ✓ Must not have any accessible surfaces which could cause burns.

Other:

- ✓ Must be readily cleanable and not present any risk of infection, sickness or contamination. (EN12182 part 5.4.1)
- ✓ Upholstery must not be ignitable. (EN 1021, parts 1 and 2, CAL 117.) All other fabrics, i.e. straps or fleece, must meet EN1021 and EN12182 part 5.
- ✓ FMEA and test results are on file in the DMR for this product.

Authorised Signature:



Kirk Wareham, VP and General Manager

December 13, 2013

Date

EU Declaration of Conformity
Owner/Approver: Operations Manager

Rev. D

December 13, 2013

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Schedule I - Medical Devices

Item	Description	Item	Description
E400	Supine Stander Accessories	K710	Rifton Support Station
E420	Small Supine Stander	K811	Small Right Arm Anchor
E430	Large Supine Stander	K812	Small Left Arm Anchor
E500	Bath System Accessories	K813	Large Right Arm Anchor
E541	Small Bath System	K814	Large Left Arm Anchor
E542	Medium Bath System	K815	Right Elbow Anchor
E543	Large Bath System	K816	Left Elbow Anchor
E800	Toilet System Accessories	K821	Hand Anchor
E806	Small Toilet System	K822	Wrist Anchor
E808	Large Toilet System	K823	Horizontal Anchor
E900	Prone Stander Accessories	K824	Grab Bar
E930	Prone Stander	R100	Rifton Tricycle Accessories
E940	Prone Stander	R120	Small Tricycle
E950	Prone Stander	R130	Medium Tricycle
K100	Dynamic Stander Accessories	R140	Large Tricycle
K110	Mini Dynamic Stander	R700	SoloLift Accessories
K130	Small Dynamic Stander	R710	SoloLift
K150	Medium Dynamic Stander	R800	Rifton Activity Chair Accessories
K170	Large Dynamic Stander	R820	Small Activity Chair
K300	Rifton TRAM Accessories	R830	Small Hi-Lo Activity Chair
K310	Rifton TRAM	R840	Medium Activity Chair
K320	Low Base Rifton TRAM	R850	Medium Hi-Lo Activity Chair
K500	Pacer Accessories	R860	Large Activity Chair
K501	Small Pacer	R870	Large Hi-Lo Activity Chair
K502	Medium Pacer	Z100	Hygiene & Toileting Accessories
K503	Large Pacer	Z110	Small Hygiene & Toileting System
K504	XL Pacer	Z120	Medium Hygiene & Toileting System
K509	Mini Pacer	Z130	Large Hygiene & Toileting System
K700	Support Station Accessories		