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

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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
_____
Kirk Wareham, VP and General Manager

December 13, 2013
_____
Date

EU DECLARATION OF CONFORMITY

Schedule I - Medical Devices

Item	Description
E400	Supine Stander Accessories
E420	Small Supine Stander
E430	Large Supine Stander
E500	Bath System Accessories
E541	Small Bath System
E542	Medium Bath System
E543	Large Bath System
E800	Toilet System Accessories
E806	Small Toilet System
E808	Large Toilet System
E900	Prone Stander Accessories
E930	Prone Stander
E940	Prone Stander
E950	Prone Stander
K100	Dynamic Stander Accessories
K110	Mini Dynamic Stander
K130	Small Dynamic Stander
K150	Medium Dynamic Stander
K170	Large Dynamic Stander
K300	Rifton TRAM Accessories
K310	Rifton TRAM
K320	Low Base Rifton TRAM
K500	Pacer Accessories
K501	Small Pacer
K502	Medium Pacer
K503	Large Pacer
K504	XL Pacer
K509	Mini Pacer
K700	Support Station Accessories

Item	Description
K710	Rifton Support Station
K811	Small Right Arm Anchor
K812	Small Left Arm Anchor
K813	Large Right Arm Anchor
K814	Large Left Arm Anchor
K815	Right Elbow Anchor
K816	Left Elbow Anchor
K821	Hand Anchor
K822	Wrist Anchor
K823	Horizontal Anchor
K824	Grab Bar
R100	Rifton Tricycle Accessories
R120	Small Tricycle
R130	Medium Tricycle
R140	Large Tricycle
R700	SoloLift Accessories
R710	SoloLift
R800	Rifton Activity Chair Accessories
R820	Small Activity Chair
R830	Small Hi-Lo Activity Chair
R840	Medium Activity Chair
R850	Medium Hi-Lo Activity Chair
R860	Large Activity Chair
R870	Large Hi-Lo Activity Chair
Z100	Hygiene & Toileting Accessories
Z110	Small Hygiene & Toileting System
Z120	Medium Hygiene & Toileting System
Z130	Large Hygiene & Toileting System