

EC DECLARATION OF CONFORMITY

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Revision No	05	
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Effective from	02-Oct-2018	

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James Leckey Design Ltd declare that the following products in all sizes, configurations and colours:

Part Prefix No	Product Name	Part Prefix No	Product Name	
LCS	Leckey Corner Sitter	102	Hi-low chassis	
LCT	Leckey Corner Sitter Table	110	Sleepform	
LES	Leckey Easy Seat	117	Mygo Seating System - Size 1	
LPT	Leckey Easy Seat Potty Trainer	137	Mygo Seating System - Size 2	
LFS/T	Leckey Totstander	118	Squiggles Stander System	
LFS	Leckey Freestander	119	Squiggles Early Sitting System	
LPS	Leckey Prone Stander	120	Squiggles Seating System	
LHZ	Leckey Horizon Stander	1 00 0 1		
LBS	Leckey Bath Support	130 Squiggles Early Activity System		
LSF	Leckey Shower Trolley	133	Kit Seating System Size 1	
ETS	Therapy stool	133	Leckey Tour Base	
EPB	Therapy Bench	135	Pal Seating system	
LAB	Leckey Advance Bath Chair	139	Kit seating system Size 2	
164	Scooot Seat	143	Mygo Stander Size 1 & 2	
165	Playpak 147		Leeway Pelvic Cradle	
169	GOTO Shop Seat	151	Everyday Activity Seat 1, 2 &3	
155	Proximal Support Harnesses	149	Comfee Seat Size 1, 2 & 3	
157	GOTO Seat Size 1 & 2	161	Mygo Max Seating System	
160	UpSee Walking Harness XS, S, M, L	164	Scooot Seat	
165	Playpak	169	GOTO Shop Seat	
173	MyWay Walker	176	Splashy Bath Seat	
181	GoTo Shop Commercial	184	Squiggles Abductive Stander	
189	Splashy Big Bath Seat			

Conforms to the Requirements of the Medical Device Directive 93 / 42 / EEC as amended by 2007 / 42 / EC for Class 1 medical devices.

And where applicable conforms to the requirements of the Low Voltage Directive 73/23/EEC and Electromagnetic Compatibility Regulations S.1. 1992/3080

The technical files for these products and supporting information for this Declaration of Conformity is held at our offices at the above address.

James Leckey Chief Executive Officer	Date
4	02-Oct-2018



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Appendix:

James Leckey Design also confirm that as a supplier of Class 1 Medical Devices our products meet the requirements of the following quality standards;

Standard	Description
BS EN 12182:2012	Assistive products for persons with disability - General requirements and test methods
BS EN 1985:1999	Walking Aids – General Requirements & Test Methods (Where applicable)
BS EN ISO 14971:2012	Medical Devices – Application of Risk Management to Medical Devices
ISO 16840-4:2009Ed1	Wheelchair seating – Seating systems for use in motor vehicles (Mygo, Squiggles & kit seating systems only)
BS ISO 7176-2:2001	Wheelchairs - Determination of dynamic stability of electric wheelchairs
BS ISO 7176-3:2012	Wheelchairs - Determination of effectiveness of brakes
BS ISO 7176-5:2008	Wheelchairs - Determination of dimensions, mass and manoeuvring space
BS ISO 7176-8:1998	Wheelchairs - Requirements and test methods for static, impact and fatigue strengths
BS ISO 7176-11:2012	Wheelchairs - Test dummies
BS ISO 7176-15:1996	Wheelchairs - Requirements for information disclosure, documentation and labelling
BS ISO 7176-16:2012	Wheelchairs - Resistance to ignition of postural support devices
BS ISO 7176-19:2008 Ed1	Wheelchairs - Part 19: Wheeled mobility devices for use as seats in motor vehicles (Mygo, Squiggles and Kit Seating Systems & Leckey Tour Wheelbase)
BS EN ISO 10993-5:2009	Biological evaluation of medical devices - Tests for in vitro cytotoxicity
BS EN 60601-1-2:2007	Medical electrical equipment - General requirements for basic safety and essential performance. Collateral standard. Electromagnetic compatibility. Requirements and tests
BS EN ISO 10535:2006	Hoists for transfers of disabled persons

James Leckey Chief Executive Officer	Date
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DOCUMENT HISTORY

Document No	Document Title	Revision	Nature of change	Date
LD-EC-DOC-01	EC Declaration of Conformity	02	First Issue to DQMS	03-Jun-2016
LD-EC-DOC-01	EC Declaration of Conformity	03	176 (Splashy Bath Seat) added to Product Listing	28-Apr-2017
LD-EC-DOC-01	EC Declaration of Conformity	04	181 (GoTo Shop Commercial) added to Product Listing	25-Apr-2018
LD-EC-DOC-01	EC Declaration of Conformity	05	173 (MyWay Walker), 184 (Squiggles Abductive Stander) and 189 (Splashy Big Bathseat added to Product Listing	02-Oct-2018