

	EC DECLARATION OF CONFORMITY	Document No	LD-EC-DOC-01
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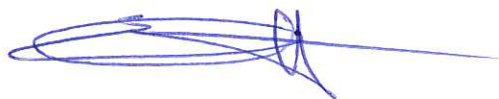
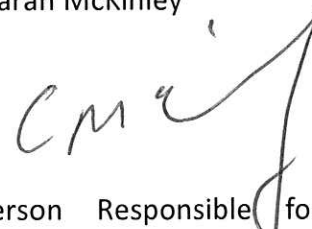
Company:	James Leckey Design Ltd 19 Ballinderry Road Lisburn BT28 2SA Northern Ireland
SRN:	XI-MF-000003572
Product Name:	Mygo Stander Trade Names: Mygo Stander Size 1, Mygo Stander Size 2, Leckey Mygo Stander Size 1, Leckey Mygo Stander Size 2
Basic UDI-DI:	05059804102StandingEW
Intended Purpose	The devices are intended to assist children that cannot stand or maintain a standing position independently as part of a supported weight bearing program.
James Leckey Design Ltd declare under our sole responsibility that the product(s) to which this declaration relates is a Class I device and conforms to the requirements of the Regulation (EU) 2017/745 on medical devices. And where applicable conforms to the requirements of the Low Voltage Directive 73/23/EEC and Electromagnetic Compatibility Regulations S.1s 1992/3080	

Name:

Erwin McKee

Ciaran McKinley

Signature

Function

R&D Director

Person Responsible for
Regulatory Compliance

Place and date of issue

Lisburn 12th May 2021Lisburn 12th May 2021

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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 listing.	28-Apr-2017
LD-EC-DOC-01	EC Declaration of Conformity	04	181 (GoTo Shop Commercial) added to 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 listing.	02-Oct-2018
LD-EC-DOC-01	EC Declaration of Conformity	06	182 (WeGo Pushchair) added to listing.	08-Apr-2019
LD-EC-DOC-01	EC Declaration of Conformity	07	188 (Leckey Therapy Bench), 187 Leckey Connect added to listing	9-May-2019
LD-EC-DOC-01	EC Declaration of Conformity	08	Updated to current CEO. Also added 161 – MyGo Max which was mistakenly removed.	18-Aug-2020
LD-EC-DOC-01	EC Declaration of Conformity	09	Updated to include 185 (Mygo Seating System - Size 3)	21-Sep-2020
LD-EC-DOC-01	EC Declaration of Conformity	10	Updated to remove references to all products, include double signature from R&D Director and PRRC	06-Oct-2020

ES ATBILSTĪBAS DEKLARĀCIJA

Uzņēmums:	James Leckey Design Ltd 19 Ballinderry Road Lisburn BT28 2SA Northern Ireland
SRN:	XI-MF-000003572
Ierīces nosaukums:	Mygo vertikalizators Komerccnosaukumi: Mygo Stander 1. izmērs, Mygo Stander 2. izmērs, Leckey Mygo Stander 1. izmērs, Leckey Mygo Stander 2. izmērs
Bāzes UDI-DI:	05059804102StandingEW
Paredzamā lietošana:	Ierīces ir paredzētas, lai palīdzētu bērniem, kuri nevar patstāvīgi stāvēt vai noturēties stāvus kā daļa no atbalstītas svara nešanas programmas.
James Leckey Design Ltd, ņemoties pilnu atbildību, apliecina, ka produkti, uz kuriem attiecas šī deklarācija, ir I klases ierīce un atbilst Regulas (ES) 2017/745 prasībām par medicīnas ierīcēm.	
Un, kur piemērojams, atbilst Zemsprieguma direktīvas 73/23/EEK prasībām un Elektromagnētiskās saderības noteikumiem S. 1s 1992/3080	

Vārds:	Erwin McKee	Ciaran McKinley
Paraksts	(paraksts)	(paraksts)
Amats	Attīstības nodaļas vadītājs	Atbildīgais par regulatoro jomu
Izdošanas vieta un datums	Lisburna, 12.05.2021.	Lisburna, 12.05.2021.