

LECKEY °	EC DECLARATION OF CONFORMITY	Document No	LD-EC-DOC-01
		Revision No	10
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		Effective from	06-Oct-2020

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

Name:

Erwin McKee

Ciaran McKinley

Signature

Function


R&D Director

Person Responsible for
Regulatory Compliance

Place and date of issue

Lisburn 12th May 2021

Lisburn 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