

Company:	James Leckey Design Ltd 19 Ballinderry Road Lisburn BT28 2SA Northern Ireland
SRN:	XI-MF-000003572
Product Name:	Splashy Big Trade Names: Splashy Big, Firefly Splashy Big
Basic UDI-DI:	05059804104Bathing7L
Intended Purpose	Bathing Supports are intended to support children and young adults who have mild to complex postural needs that disrupt the ability to sit without external support. All devices are intended to be used within a bath or shower to facilitate personal care. Splashy can additionally be used outdoors for recreational purposes such as use at a beach or water park.

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.

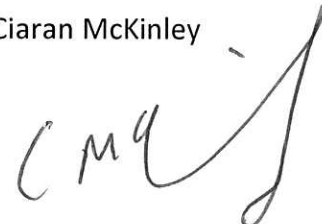
And where applicable conforms to the requirements of the Low Voltage Directive 73/23/EEC and Electromagnetic Compatibility Regulations S.1s 1992/3080

Name:

Erwin McKee

Ciaran McKinley

Signature



Function

R&D Director

Person Responsible for
Regulatory Compliance

Place and date of issue

Lisburn 13th May 2021Lisburn 13th May 2021

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