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|----------------------------------------------------------------------------------|------------------------------|----------------|--------------|
|  | EC DECLARATION OF CONFORMITY | Document No    | LD-EC-DOC-01 |
|                                                                                  |                              | Revision No    | 10           |
|                                                                                  |                              | Page           | 1 of 2       |
|                                                                                  |                              | Effective from | 06-Oct-2020  |

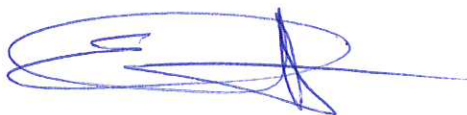
|                                                                                                                                                                                                                                                                                                                                                                                                  |                                                                                                                                                            |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Company:                                                                                                                                                                                                                                                                                                                                                                                         | James Leckey Design Ltd<br>19 Ballinderry Road<br>Lisburn<br>BT28 2SA<br>Northern Ireland                                                                  |
| SRN:                                                                                                                                                                                                                                                                                                                                                                                             | XI-MF-000003572                                                                                                                                            |
| Product Name:                                                                                                                                                                                                                                                                                                                                                                                    | Squiggles+<br>Trade Names: Squiggles+, Leckey Squiggles+                                                                                                   |
| 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&amp;D Director

Person Responsible for  
Regulatory Compliance

Place and date of issue

Lisburn 13<sup>th</sup> May 2021Lisburn 13<sup>th</sup> 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<br>19 Ballinderry Road<br>Lisburn<br>BT28 2SA<br>Northern Ireland                                                         |
| SRN:                                                                                                                                                                                                | XI-MF-000003572                                                                                                                                   |
| Ierīces nosaukums:                                                                                                                                                                                  | Squiggles+<br>Komerccnosaukumi: Squiggles+, Leckey Squiggles+                                                                                     |
| 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, uzņemoties 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.           |