

Declaration of Conformity

Krabat AS
Ravnsborgveien 56
1395 Hvalstad
NORWAY



Tel: + 47 66 77 73 00
Faks: + 47 66 77 73 01
Web: www.krabat.com

As manufacturer, Krabat AS, with sole responsibility declares that the *Krabat Jockey Lite* active chair, meets the provisions of the Council Directive 93/42/EEC for medical devices as amended by 2007/47/EC.

These products are classified as Class I.

Moreover we declare valid the correspondence of this product with following norms / nominal document:

- EN 1335, Office chairs

As a result of the correspondence with the mentioned norms, the product is entitled to CE approval.

Date: 12/10/2015
Place: Hvalstad, Norway
Name: Fredrik Brodtkorb
Function: Managing Director

Signature:

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As manufacturer, Krabat AS, with sole responsibility declares that the Krabat Sheriff (Krabat Sheriff S1, Krabat Sheriff S2, Krabat Sheriff S1 Plus and Krabat Sheriff S2 Plus) wheelchair for children, conforms to the requirements of the 93/42/EEC Guidelines. Krabat Sheriff is classified as I.

Moreover we declare valid the correspondence of this product with following norms / nominal document:

- EN 12183:2009(E) including ISO 7176-1, ISO 7176-3, ISO 7176-8. Also in accordance with ISO 7176-5

As a result of the correspondence with the mentioned norms, the product is entitled to CE approval.

Date: 11/11/2014
Place: Hvalstad, Norway
Name: Fredrik Brodtkorb
Function: Managing Director

Signature:

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1395 Hvalstad
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As manufacturer, Krabat AS, with sole responsibility declares that the *Krabat Jockey (manual and electric)*, *Krabat Jockey Plus (manual and electric)*, meets the provisions of the Council Directive 93/42/EEC for medical devices as amended by 2007/47/EC.

Krabat Jockey is classified as Class I.

Moreover we declare valid the correspondence of this product with following norms / nominal document:

- EN 12182:2012, Technical aids for disable persons and methods.

As a result of the correspondence with the mentioned norms, the product is entitled to CE approval.

Date: 06/08/2014
Place: Hvalstad, Norway
Name: Fredrik Brodtkorb
Function: Managing Director

Signature:

EC DECLARATION OF CONFORMITY

Medical Device Manufacturer:

James Leckey Design Ltd
19C Ballinderry Road
Lisburn
BT28 2SA
United Kingdom

Phone: + 44 (0) 28 9260 0750
Fax: + 44 (0) 28 9260 0799
E-mail: info@leckey.com
Internet: www.leckey.com

James Leckey Design Ltd declares that the Firefly GoTo Seat, in all sizes, configurations and colours, along with its accessories, conforms to the Essential Requirements of the Medical Device Directive 93 / 42 / EEC (as amended by 2007 / 42 / EC)

Medical Device Name Firefly GoTo Seat & accessories

MDD Classification Class 1 (Classification Rule 1)

Conformity Assessment Route

In accordance with article 11 of Council Directive 93 / 42 / EEC, and for the purpose of CE marking the Firefly GoTo Seat and its accessories, James Leckey Design Ltd followed the procedure relating to the EC Declaration of Conformity set out in Annex VII of the Directive.

Conformity was demonstrated by converting Annex I (Essential Requirements) of the Directive into a checklist, enabling James Leckey Design Ltd to ensure that all of the essential requirements have been met.

The technical documentation for this product and supporting information for this Declaration of Conformity is held at our offices at the above address.

Approved by:
Gary O'Hagan
Managing Director

Date:



26th November 2015

EC DECLARATION OF CONFORMITY

Medical Device Manufacturer:

James Leckey Design Ltd
19C Ballinderry Road
Lisburn
BT28 2SA
United Kingdom

Phone: + 44 (0) 28 9260 0750
Fax: + 44 (0) 28 9260 0799
E-mail: info@leckey.com
Internet: www.leckey.com

James Leckey Design Ltd declares that the Firefly Scoot seat, in all sizes, configurations and colours, along with its accessories, conforms to the Essential Requirements of the Medical Device Directive 93 / 42 / EEC (as amended by 2007 / 42 / EC)

Medical Device Name Firefly Scoot seat & accessories

MDD Classification Class 1 (Classification Rule 1)

Conformity Assessment Route

In accordance with article 11 of Council Directive 93 / 42 / EEC, and for the purpose of CE marking the Firefly Scoot seat and its accessories, James Leckey Design Ltd followed the procedure relating to the EC Declaration of Conformity set out in Annex VII of the Directive.

Conformity was demonstrated by converting Annex I (Essential Requirements) of the Directive into a checklist, enabling James Leckey Design Ltd to ensure that all of the essential requirements have been met.

The technical documentation for this product and supporting information for this Declaration of Conformity is held at our offices at the above address.

Approved by:
Gary O'Hagan
Managing Director

Date:



6th January 2016

EC DECLARATION OF CONFORMITY

Medical Device Manufacturer:

James Leckey Design Ltd
19C Ballinderry Road
Lisburn
BT28 2SA
United Kingdom

Phone: + 44 (0) 28 9260 0750
Fax: + 44 (0) 28 9260 0799
E-mail: info@leckey.com
Internet: www.leckey.com

James Leckey Design Ltd declares that the Firefly Playpak, in all sizes, configurations and colours, along with its accessories, conforms to the Essential Requirements of the Medical Device Directive 93 / 42 / EEC (as amended by 2007 / 42 / EC)

Medical Device Name Firefly Playpak & accessories
MDD Classification Class 1 (Classification Rule 1)

Conformity Assessment Route

In accordance with article 11 of Council Directive 93 / 42 / EEC, and for the purpose of CE marking the Firefly Playpak and its accessories, James Leckey Design Ltd followed the procedure relating to the EC Declaration of Conformity set out in Annex VII of the Directive.

Conformity was demonstrated by converting Annex I (Essential Requirements) of the Directive into a checklist, enabling James Leckey Design Ltd to ensure that all of the essential requirements have been met.

The technical documentation for this product and supporting information for this Declaration of Conformity is held at our offices at the above address.

Approved by:
Gary O'Hagan
Managing Director

Date:



6th January 2016

EC DECLARATION OF CONFORMITY

Medical Device Manufacturer:

James Leckey Design Ltd
19C Ballinderry Road
Lisburn
BT28 2SA
United Kingdom

Phone: + 44 (0) 28 9260 0750
Fax: + 44 (0) 28 9260 0799
E-mail: info@leckey.com
Internet: www.leckey.com

James Leckey Design Ltd declares that the Firefly Upsee Walking Harness, in all sizes, configurations and colours, along with its accessories, conforms to the Essential Requirements of the Medical Device Directive 93 / 42 / EEC (as amended by 2007 / 42 / EC)

Medical Device Name Firefly Upsee Walking Harness & accessories

MDD Classification Class 1 (Classification Rule 1)

Conformity Assessment Route

In accordance with article 11 of Council Directive 93 / 42 / EEC, and for the purpose of CE marking the Firefly Upsee Walking Harness and its accessories, James Leckey Design Ltd followed the procedure relating to the EC Declaration of Conformity set out in Annex VII of the Directive.

Conformity was demonstrated by converting Annex I (Essential Requirements) of the Directive into a checklist, enabling James Leckey Design Ltd to ensure that all of the essential requirements have been met.

The technical documentation for this product and supporting information for this Declaration of Conformity is held at our offices at the above address.

Approved by:
Gary O'Hagan
Managing Director



Date:

6th January 2016

EC DECLARATION OF CONFORMITY

Medical Device Manufacturer:

James Leckey Design Ltd
19C Ballinderry Road
Lisburn
BT28 2SA
United Kingdom

Phone: + 44 (0) 28 9260 0750
Fax: + 44 (0) 28 9260 0799
E-mail: info@leckey.com
Internet: www.leckey.com

James Leckey Design Ltd declares that the Firefly Splashy Bath Seat, in all configurations and colours, along with its accessories, conforms to the Essential Requirements of the Medical Device Directive 93 / 42 / EEC (as amended by 2007 / 42 / EC)

Medical Device Name Firefly Splashy Bath Seat & accessories

MDD Classification Class 1 (Classification Rule 1)

Conformity Assessment Route

In accordance with article 11 of Council Directive 93 / 42 / EEC, and for the purpose of CE marking the Firefly GoTo Shop Seat and its accessories, James Leckey Design Ltd followed the procedure relating to the EC Declaration of Conformity set out in Annex VII of the Directive.

Conformity was demonstrated by converting Annex I (Essential Requirements) of the Directive into a checklist, enabling James Leckey Design Ltd to ensure that all of the essential requirements have been met.

The technical documentation for this product and supporting information for this Declaration of Conformity is held at our offices at the above address.

Approved by:
Gary O'Hagan
Managing Director

Date:



26/01/17

EC DECLARATION OF CONFORMITY

James Leckey Design Ltd
 19 Ballinderry Road
 Lisburn
 BT28 2SA

Phone: + 28 9260 0750
 Fax: + 28 9260 0799
 E-mail: info@leckey.com
 Internet: www.leckey.com

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

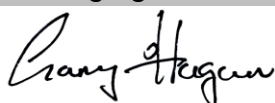
Art Prefix No	Product Name	Art Prefix No	Product Name
CAS	Contoured Advance Seat	102	Hi-low chassis
HC	Home Chair	110	Sleepform
MAS	Mobile Advance Seat	117	Mygo Seating System - Size 1
LCS	Leckey Corner Sitter	137	Mygo Seating System - Size 2
LCT	Leckey Corner Sitter Table	118	Squiggles Stander System
LES	Leckey Easy Seat	119	Squiggles Early Sitting System
LPT	Leckey Easy Seat Potty Trainer	120	Squiggles Seating System
LFS/T	Leckey Totstander	122	Squiggles Saddle Seat
		122	Squiggles Easy chassis
LFS	Freestander	129	Squiggles Stander – Mobile Chassis
LPS	Prone Stander	130	Squiggles Early Activity System
LHZ	Leckey Horizon Stander	133	Kit Seating System Size 1
LAB	Leckey Advance Bathchair	133	Leckey Tour Base
LBS	Leckey Bath Support	135	Pal Seating System
LSF	Leckey Shower Trolley	139	Kit Seating System Size 2
LTS	Leckey Toilet Seat	143	Mygo Stander Size 1 & 2
OTS	Over Toilet Seat	147	Leeway Pelvic Cradle
WT	Waist Coat	151	Everyday Activity Seat 1 & 2
ETS	Therapy stool		
EPB	Therapy Bench		
STJ	Springfield table - Junior		
STS	Springfield table - Senior		

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

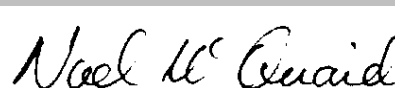
And where applicable conforms to the requirements of the Low Voltage Directive 73/23/EEC and Electromagnetic Compatibility Regulations S.1. 1992/3080

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

Gary O'Hagan
 Managing Director



Noel McQuaid
 Technical Director



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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;

Technical Aids for Disabled Persons EN 12182 (All)

Walking Aids – General Requirements & Test Methods EN1985 (Where applicable)

Medical Devices – Application of Risk Management to Medical Devices EN ISO 14971:2009 (All)

Wheelchair seating – Seating devices for use in motor vehicles EN ISO 16840/4 (Mygo, Squiggles & kit seating systems only)

Wheelchairs - EN ISO 7176 parts 1-22 (Mygo, Squiggles and Kit Seating Systems & Leckey Tour Wheelbase)

Biological evaluation of medical devices Part 5 Tests for invitro cytotoxicity ISO 10993-5 (All)

EN/IEC 60601-1-2 – EMC Compliance Requirements for Medical Electrical Equipment

Gary O'Hagan
Managing Director



Noel McQuaid
Technical Director

