

EU Declaration of Conformity

Samsvarserklæring

We Hepro AS, dept. Krabat
Ravnsborgveien 56,
1395 Hvalstad, Norway

Phone: +47 66777300
Web: www.krabat.no



hereby declare that this DoC is issued under our sole responsibility as a manufacturer, and belongs to the following product(s):

erklærer herved, på eget ansvar, at vi som produsent har utstedt denne samsvarserklæring for følgende produkt(er):

Art. No.	Name/model	Description	GMN
300-1001	Krabat Jockey, size 1, manual	Lifting chair for disabled children	709003367300KJKYx22
300-4001	Krabat Jockey, size 2, manual	Lifting chair for disabled children	709003367300KJKYx22
300-5000	Krabat Jockey, size 1, electric	Lifting chair for disabled children	709003367300KJKYx22
300-5002	Krabat Jockey, size 2, electric	Lifting chair for disabled children	709003367300KJKYx22

The product(s) mentioned above is classified as Class 1 and comply with the following directives and regulations:

Produktet / produktene nevnt ovenfor er klassifisert som risikoklasse 1 og oppfyller følgende direktiver og forskrifter

Directive/ regulation	Description
EU 2017/745	Regulation on Medical Devices
EN 12182:2012	Technical aids for disabled persons and methods
ISO 14971:2007	Risk Management

For the evaluation of the compliance with these Directives and Regulations, the following harmonized standards/ requirements have been applied:

Følgende harmoniserte standarder / krav er brukt for evaluering av samsvar med disse direktiver og forskrifter:

Standard	Description
ISO 60601-1:2005 (3 rd ed.) + CORR. 1:2006 + CORR. 2:2007 + A1:2012	Safety
ISO 60601-1-11:2015	Home healthcare
ISO 60601-1-6:2010 + A1:2013 + IEC 62366:2007 + A1:2014	Usability
ISO 60601-1-2:2014	EMC
ISO 62366:2007 + A1:2014	Usability
NS-EN 1021-1:2014	Flameability
NS-EN 1021-2:2014	Flameability

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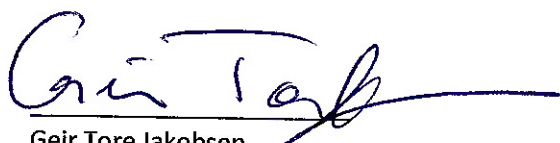
Certificate No. 010 issued by Kiwa Technological Institute certifies conformity with the management system requirements of NS-EN-ISO 9001:2015, Quality management systems, and NS-EN ISO 14001:2015, Environmental management systems.

Sertifikat nr. 010 utstedt av Kiwa Teknologisk Institutt viser godkjent overensstemmelse med styringssystemkravene i henhold til NS-EN-ISO 9001:2015, Ledelsessystemer for kvalitet, og NS-EN ISO 14001:2015, Ledelsessystemer for miljø.

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

Som et resultat av samsvar med de nevnte normer, kvalifiserer produktet til å bli CE-merket.

Hvalstad , 28.02.2020



Geir Tore Jakobsen
Managing Director/ CEO

Picture(s) of product(s):



Krabat Jockey, str. 1

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Art. No.	Name/model	Description	GMN
300-4004	Krabat Jockey Lite, size 1	Lifting chair for disabled children	709003367300KJLTxZM
300-4002	Krabat Jockey Lite, size 2	Lifting chair for disabled children	709003367300KJLTxZM
300-4009	Krabat Jockey Lite, size 3	Lifting chair for disabled children	709003367300KJLTxZM

The product(s) mentioned above is classified as Risk class 1 and comply with the following directives and regulations:

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Directive/ regulation	Description
EU 2017/745	Regulation on Medical Devices
EN 12182:2012	Technical aids for disabled persons and methods
ISO 14971:2007	Risk Management

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Standard	Description
NS-EN 1335-1:2000	Office work chairs
NS-EN 1335-2:2009	Office work chairs
NS-EN 1335-3:2009	Office work chairs
NS-EN 1021-1:2014	Flameability
NS-EN 1021-2:2014	Flameability

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Hvalstad , 28.02.2020



Geir Tore Jakobsen
Managing Director/ CEO

Picture(s) of product(s):



Krabat Jockey Lite sz. 2



Krabat Jockey Lite sz. 3

Internal Test Report

Krabat Pilot



Report no.:	KT-KP-12182-0002
Tested at:	Hepro AS, dept. Krabat, Ravnsborgveien 56, 1395 Hvalstad, Norway
Date:	03.05.2016
Manufacturer:	Hepro, avd. Krabat
Sample:	Krabat Pilot
Serial number:	071
Issued by:	AS
Result	Pass

Test in compliance with
EN12182:2012

12182:2012	References	Comments
4. General requirements		
4.1. Risk analysis	EN ISO 14971	Risk Management Report for Krabat Pilot performed according to ISO 14971
4.2. Intended performance and technical documentation	EN 1335	Covered by this standard
4.3. Clinical evaluation and investigation	ISO 9001 93/42/EEC	Clinical Evaluation Report performed according to EU 2017/745
4.4. Assistive products that can be dismantled	n/a	
4.5. Fasteners	n/a	
4.6. Mass limit	100 kg	Described in the user manual
4.7. Immobilizing Means	EN ISO 14971	Covered by the risk evaluation
4.8. Design requirements in relation to persons with cognitive impairments.		Covered by Risk Management Report and described in technical documentation. Product intended for children with physical- and/ or mental disabilities.
5. Materials		
5.1. Manufacturers should, wherever possible, use materials that can be recycled for further use.		The product is designed to be serviced and recycled. All materials are recyclable.
5.2. Flammability		
5.2.1. General	EN 1021	Described in the user manual
5.2.2. Upholstered parts, mattresses, bed bases and bedding		Covered by the user manual
5.2.3. Upholstered parts	EN 1021-1 and EN 1021-2	Tested according to EN 1021-1 / -2 and passed.
5.2.4. Mattresses and bed bases	n/a	
5.2.5. Bedding	n/a	
5.2.6. Molded parts	n/a	
5.3. Biocompatibility and toxicity	n/a	
5.4. Contaminants and residue		
5.4.1. General	n/a	There is no contaminants or residue in the product
5.4.2. Substances which may leak from an assistive product in intended use and in fault condition	n/a	
5.5. Infection and microbiological contamination	n/a	Product for use in private homes, not in special env.
5.5.1. Cleaning and disinfection		Cleaning is described in the user manual

5.5.2. Animal tissue	n/a	
5.6. Resistance to corrosion		All metal parts are treated to withstand corrosion.
6. Emitted sound and vibration	n/a	
6.1. Noise and vibration		
6.2. Sound levels and frequencies of audible warning devices		
6.3. Feedback		
7. Electromagnetic compatibility	n/a	
7.1. General		
7.2. Emissions		
7.3. Immunity		
7.4. Power frequency magnetic field immunity		
8. Electrical safety	n/a	
8.1. General		
8.2. Electrical systems		
8.3. Continuity of power supply		
8.4. Battery powered assistive products		
8.5. Circuit protection		
8.6. Electronic programmable systems		
8.7. Electrically heated blankets, pads and similar flexible heating appliances		
8.8. Assistive products with skin contact electrodes		
8.9. Ingress of liquids		
9. Overflow, spillage, leakage and ingress of liquids	n/a	
9.1. Overflow		
9.2. Spillage		
9.3. Leakage		
9.4. Ingress of liquids		
9.4.1. Requirements		
9.4.2. Test method		
10. Surface temperature		See Risk Management Report for description, also mentioned in the User Manual
11. Sterility	n/a	
12. Safety of moving parts		
12.1. Squeezing		Pass
12.2. Mechanical wear		All parts subject to mechanical wear is accessible for inspection
12.3. Emergency stopping functions	n/a	
13. Prevention of traps for the human body		
13.1. Holes and clearances		Pass
13.2. V-shaped openings	n/a	

14. Folding and adjusting mechanisms		Described in Risk Management Report. No folding or adjusting mechanisms which may cause a hazard.
15. Carry handles		
15.1. General	n/a	
15.2. Requirement	n/a	
15.3. Test methods	n/a	
16. Assistive products which support or suspend users		
16.1. General		The product will not become detached, exhibit cracking, be permanently deformed, lose stability or have any failure when tested as specified in 16.2 and 16.3
16.2. Static force		Pass
16.3. Dynamic force		Pass
16.4. Requirements and test methods for tips		
16.4.1. General		Described in Risk Management Report. The product is safe in its use
16.4.2. Friction of tips	n/a	
16.4.3. Durability of tips	n/a	
17. Portable and mobile assistive products	n/a	
18. Surfaces, corners, edges and protruding parts		Described in Risk Management Report.
19. Handheld assistive products	n/a	
20. Small parts	n/a	
21. Stability		Pass
22. Forces in soft tissues of the human body	n/a	
23. Ergonomic principles		The product's main purpose is to support small children learning to crawl. It is designed to give these children support and give them a sense of safety when crawling.
24. Requirements for information supplied by the manufacturer		
24.1. General	EU 2017/745	Information supplied according to EU 2017/745
24.2. Instruction for use		
24.2.1. Pre-sale information	EN 12182	

24.2.2. User information	n/a	User information supplied by the performing therapist
24.2.3. Service information	ISO 14971	See User Manual
24.2.4. Labeling	EU 2017/745	The product is labeled with permanent labels that meets the requirement in EU 2017/745
25. Packaging	n/a	The packaging gives appropriate protection against damage
26. Test report	EN 12182:2012	Tested at Hepro AS, dept Krabat's facilities.

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Art. No.	Name/model	Description	GMN
700-1114	Krabat Runner, size 1	Kick bike/ rollator for disabled children	709003367700KRNR1ZT

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EN 12182:2012	Technical aids for disabled persons and methods
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Standard	Description
ISO 11199-2:2005	Walking aid manipulated w/ both hands

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Hvalstad , 28.02.2020



Geir Tore Jakobsen
Managing Director/ CEO

Picture(s) of product(s):



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Art. No.	Name/model	Description	GMN
400-3004	Krabat Sheriff S1	Wheelchair for disabled children	709003367400KSHFx2C
400-3005	Krabat Sheriff S2	Wheelchair for disabled children	709003367400KSHFx2C
400-3006	Krabat Sheriff S1 Plus	Wheelchair for disabled children	709003367400KSHFx2C
400-3007	Krabat Sheriff S2 Plus	Wheelchair for disabled children	709003367400KSHFx2C

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Standard	Description
NS-EN 12183:2009	Technical, wheelchairs
NS-EN 1021-1:2014	Flameability
NS-EN 1021-2:2014	Flameability

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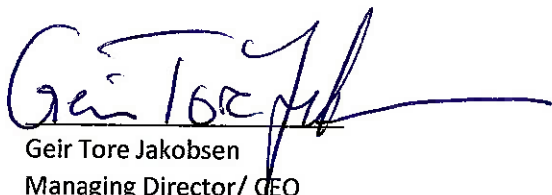
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Hvalstad , 28.02.2020



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Managing Director/ CEO

Picture(s) of product(s):



Krabat Sheriff



Krabat Sheriff Plus