

Declaration of Conformity 2021-05 Careva Harness System and Crossit Harness

This Declaration of Conformity is in accordance with Regulation (EU) 2017/745 (MDR),
and LVFS 2003:11, LVFS 2001:5

Product Name and Intended Purpose	Article Art.no and (UDI- GTIN-13)
Careva Harness System <i>Intended Use:</i> To support upright sitting position in vehicles or wheelchairs. <i>Intended Users:</i> Persons in need of body posture support.	See page 2 of this documentation
Manufacturer	Phone/email/www
Careva System AB Theres Svenssons gata 10 S-41755 Gothenburg Sweden	Phone +46 31 222800 info@careva.se www.careva.se

CONFORMITY ASSESSMENT	
Classification	Route to compliance
MDR class 1	Regulation EU 2017/745 of The European Parliament and of European Council
Risk class 1	

Careva Systems AB (org no 556511-5150) declares that the products meet the provision of the Regulation (EU) 2017/745 of the European Parliament and the Council as transposed in the national laws of the Member States.

DESCRIPTION
Careva's management system is based on the requirements in ISO 9001:2015, ISO 14001:2015 and Regulation (EU) 2017/745 article 9. The overall structure of the management system is based on Annex SL Appendix 2. (Annex SL is a high level structure for ISO standards i.e. they share the same grouping of requirements).

Signature:



Company Representative: Evastina Björk

Place of issue: Gothenburg, Sweden

Title: CEO, Company owner

Date: 2021-05-01

GTIN 13 for Careva System AB (18-05-2021)

<i>Art.nr</i>	<i>Artikel</i>	<i>GTIN 13</i>
10230	Spinal belt	7350037450013
10285	Spinal belt	7350037450020
10080	Chest belt 80 cm	7350037450037
10100	Chest belt 100 cm	7350037450044
10120	Chest belt 120 cm	7350037450051
10135	Chest belt 135 cm	7350037450068
10030	Standard buckle, (metallic)	7350037450075
10030	Standard buckle (plastic)	7350037450082
10040	Standard buckle (metallic)	7350037450099
10040	Standard buckle (plastic)	7350037450105
10150	X- long buckle (metallic)	7350037450112
10150	X long buckle (plastic)	7350037450129
10121	Shoulder belt (S)	7350037450136
10020	Shoulder belt (M)	7350037450143
10033	Shoulder belt (L)	7350037450150
10222	Hip belt (S)	7350037450167
10221	Hip belt (M)	7350037450174
10231	Hip belt (L)	7350037450181
10022	Hip belt (S) buckle included	7350037450198
10021	Hip belt (M) buckle included	7350037450204
10031	Hip belt (L) buckle included	7350037450211
10223	Combi belt(S)	7350037450228
10224	Combi belt (M)	7350037450235
10225	Combi belt (L)	7350037450242
10122	Chest buckle (S)	7350037450259
10123	Chest buckle (M;L)	7350037450266
30223	Combi KIT	7350037450273
30224	Combi KIT	7350037450280
30225	Combi KIT	7350037450297
40000	Crossit	7350037450303
40001	Seat pad	7350037450310
20000	Crossit 2.0	7350037450327
30121	Shoulder KIT	7350037450334
30020	Shoulder KIT	7350037450341
30033	Shoulder KIT	7350037450358
30080	Chest KIT	7350037450365
30100	Chest KIT	7350037450372
30120	Chest KIT	7350037450389
30222	Hip KIT	7350037450396
30221	Hip KIT	7350037450402
30231	Hip KIT	7350037450419