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## EU DECLARATION OF CONFORMITY

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### Manufacturer

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Name:	<b>Rehadapt Engineering GmbH &amp; Co. KG</b>
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Email:	<b>officeteam@rehadapt.com</b>

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This declaration of conformity is issued under the sole responsibility of the manufacturer:

### Object of the declaration

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Product group:	<b>Rehadapt frame clamps</b>
Description:	Clamps that are semi-permanently attached to the frame of wheelchairs through different clamping methods. Those clamps are used as the base for Rehadapt wheelchair mounts.
Basic UDI-DI:	<b>++B896FrameClampsK3</b>
Article numbers:	The products encompassed in this product family are listed in the table on pages 2 and 3.
Classification:	<b>Class 1 medical devices</b>

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The object of the declaration described above is in conformity with the relevant Union harmonization legislation:

- Medical Device Regulation 2017/745

References to the relevant harmonized standards used, or references to the specifications in relation to which conformity is declared:

- EN ISO 13485:2016: Medical devices – Quality management systems – Requirements for regulatory purposes
- EN ISO 14971:2019 Application of risk management to medical devices

### Additional information

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N/A

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Signed for and on behalf of:



Ulrich K Ehlert  
CEO

List of medical devices belonging to the product group "Rehadapt frame clamps"

Art. Nr.	Name	UDI-DI
11.1119	M3D RKL 19	*+B89611111903*
11.1120	M3D RKL 20	*+B8961111200_*
11.1121	M3D RKL 21	*+B8961111210\$*
11.1122	M3D RKL 22	*+B8961111220/*
11.1123	M3D RKL 23	*+B8961111230+*
11.1125	M3D RKL 25	*+B89611112500*
11.1126	M3D RKL 26	*+B89611112601*
11.1128	M3D RKL 28	*+B89611112803*
11.1129	M3D RKL 29	*+B89611112904*
11.1130	M3D RKL 30	*+B8961111300\$*
11.1132	M3D RKL 32	*+B8961111320+*
11.1134	M3D RKL 34	*+B89611113400*
11.1135	M3D RKL 35	*+B89611113501*
11.1136	M3D RKL 36	*+B89611113602*
11.1192	M3D RKL Sunrise Medical	*+B89611119204*
11.1193	M3D RKL Leggero	*+B89611119305*
11.1138	M3D RKL 38	*+B89611113804*
11.1140	M3D RKL 40	*+B8961111400/*
11.1194	M3D RKL R82 Multiframe	*+B89611119406*
11.1142	M3D RKL 42	*+B8961111420%*
11.1145	M3D RKL 45	*+B89611114502*
11.1195	M3D RKL Rifton Pacer	*+B89611119507*
11.1416	M3D RKL-T 16	*+B89611141603*
11.1419	M3D RKL-T 19	*+B89611141906*
11.1420	M3D RKL-T 20	*+B8961114200+*
11.1421	M3D RKL-T 21	*+B8961114210%*
11.1422	M3D RKL-T 22	*+B89611142200*
11.1423	M3D RKL-T 23	*+B89611142301*
11.1424	M3D RKL-T 24	*+B89611142402*
11.1425	M3D RKL-T 25	*+B89611142503*
11.1426	M3D RKL-T 26	*+B89611142604*
11.1427	M3D RKL-T 27	*+B89611142705*
11.1428	M3D RKL-T 28	*+B89611142806*
11.1429	M3D RKL-T 29	*+B89611142907*
11.1430	M3D RKL-T 30	*+B8961114300%*
11.1432	M3D RKL-T 32	*+B89611143201*
11.1065	M3D RKL-E30	*+B89611106503*
11.1060	M3D RKL-E30-70	*+B8961110600+*
11.1068	M3D Permobil UniTrack	*+B89611106806*
11.1069	M3D T-Nut 16 x 6.5	*+B89611106907*
11.1077	M3D T-Nut 10.5 x 4	*+B89611107706*
11.1066	M3D T-Nut 23 x 7	*+B89611106604*

11.1072	M3D Item P5	*+B89611107201*
11.1067	M3D RKL T-Nut Sunrise Medical	*+B89611106705*
11.1064	M3D RKL T-Nut Karma	*+B89611106402*
11.1062	M3D RAD-Per Uni	*+B89611106200*
11.1073	M3D RKL M6	*+B89611107302*
11.1070	M3D RKL M8	*+B8961110700%*
11.1075	M3D RKL M8 Mini	*+B89611107504*
11.1074	M3D Adapter Ring	*+B89611107403*
11.1071	M3D RKL-Kimba Neo	*+B89611107100*
11.1079	M3D RKL-Madita-Fun	*+B89611107908*
14.1116	L3D 10-Base E16	*+B89614111603*
14.1111	L3D 10-Base R10	*+B8961411110+*
14.1115	L3D 10-Base R11	*+B89614111502*
14.1110	L3D 10-Base R13	*+B8961411100/*
14.1114	L3D 10-Base R14	*+B89614111401*
14.1112	L3D 10-Base R15	*+B8961411120%*
14.1113	L3D 10-Base R16	*+B89614111300*
12.1000	M3D Base SuperClamp	*+B8961210000-*
14.1118	L3D 16-Base SK Pin	*+B89614111805*
14.1170	L3D 16-Base SK Connect 16	*+B89614117003*
14.1171	L3D 16-Base SK Connect 16 QS	*+B89614117104*
14.1172	L3D 10-Base SK Connect 10	*+B89614117205*
14.1173	L3D 10-Base SK Connect 10 QS	*+B89614117306*
14.1174	L3D 10 MiniClamp QS	*+B89614117407*