

CE Declaration of Conformity

F03-024

Rev: 5.0

Eigner: V-Ent

Doc No: 100664-J

KONFORMITÄTSERKLÄRUNG / DECLARATION OF CONFORMITY

Name und Anschrift des Herstellers
Name and address of the manufacturer

Pearl Technology AG
Wiesenstrasse 33
8952 Schlieren
Switzerland

Wir erklären in alleiniger Verantwortung, dass / *We declare under our sole responsibility that*

Pearltec Lagerungshilfen * bestehend aus folgenden Produktfamilien
Pearltec Positioning Aids * including following product families

Multipad
Cover
Crania
CT HeadFix
BabyFix
PearlFit
ProFoam
CT Table Cover
ProBelt
FoamFit
Beinhaltegerät
Foam
Sandbag

mit/ *with* Basic UDI-DI: siehe Anhang / *see Appendix*

der Klasse I, Regel 1 / *of class I, rule 1*

allen Anforderungen der Medizinprodukteverordnung (EU) 2017/745 (MDR) entsprechen, die anwendbar sind.
meet all the provisions of the regulation (EU) 2017/745 (MDR) which apply to it.

* Allgemeiner Produktname; Weitere Informationen finden Sie auf Seite 2 dieses Dokuments

* *General Product Name; Refer to page 2 of this document for further details.*

Konformitätsbewertungsverfahren

Verordnung EU MDR 2017/745 Artikel 52

Erstellung der Konformitätserklärung gemäss Artikel 19 nach Ausarbeitung der Technischen Dokumentation entsprechend den Anhängen II und III der EU MDR 2017/745

Medical Device Regulation Assessment Route

Regulation EU MDR 2017/745 article 52

Issuing of the Declaration of Conformity in accordance with Article 19 after drawing up the technical documentation laid out in Annexes II and III of the EU MDR 2017/745

EU Authorised Representative:

Advena Limited. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta (SRN: MT-AR-000000234)

Pearl Technology AG
Wiesenstrasse 33
CH-8952 Schlieren
Switzerland
SRN: CH-MF-000018100

Datum:

22.05.2024

Unterschrift:

T. Müller

Dr. Thomas Müller, Direktor, Pearl Technology AG

Diese Konformitätserklärung ist gültig bis:
This Declaration of Conformity is valid until:

21.05.2026

Diese EU-Konformitätserklärung verliert ihre Gültigkeit, wenn der oben genannte Artikel ohne ausdrückliche Zustimmung des Unternehmens Pearl Technology AG umgebaut oder verändert wird.

This EU Declaration of Conformity loses its validity if the above product is altered or modified without expressed approval of Pearl Technology AG.

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Anwendbare Normen/ Applicable Standards

Die vorliegende Erklärung entspricht auch den folgenden europäischen Normen und Gemeinsamen Spezifikationen (GS):

This present declaration is also in conformity with the following European standards and Common Specifications (CS):

2017/745/EU	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 concerning Medical Devices
EN ISO 13485:2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971:2019	Medical Devices – Application of Risk Management to Medical Devices
EN ISO 15223-1:2021	Medical devices. Symbols to be used with information to be supplied by the manufacturer - General requirements
EN ISO 20417:2021	Medical devices. Information to be supplied by the manufacturer

Angewandte harmonisierte Normen, nationale Normen oder andere normative Dokumente auf Checkliste **F03-008**
*Applied harmonized standards, national standards or other normative documents according to checklist **F03-008***

Zweckbestimmung / Intended use

Kurzzeitige Patientenpositionierung und -stabilisierung während invasiver und nichtinvasiver Verfahren zur Anwendung auf der intakten Haut.

Short-term patient positioning and stabilization device during invasive and non-invasive procedures to be used on intact patient's skin.

Produktliste Pearltec Lagerungshilfen / Product Listing Pearltec Positioning Aids

REF	Product name	Basis UDI	GMDN
Product family Multipad			
1012	Multipad Standard	764017806MultipadYC	61131
1022	Multipad Plus	764017806MultipadYC	61131
1071	Multipad Slim	764017806MultipadYC	61131
1104	Multipad Ear	764017806MultipadYC	61131
1108	Multipad Bendv	764017806MultipadYC	61131
5004	Multipad Research Kit	764017806MultipadRKitQW	61131
5006	Neuro Kit	764017806MultipadRKitQW	61131
Product familv Crania			
1001	Crania Adult	764017806Crania58	61132
1004	Crania Child	764017806Crania58	61132
Product familv CT HeadFix			
1105	CT HeadFix	764017806CTHeadFixCP	61132
Product familv BabyFix			
1107	BabyFix Cocoon	764017806BabyFixEK	61131
Product familv Cover			
1101	Cover Multipad 100p	764017806CoverUB	61049
1106	Cover Headphones 100p	764017806CoverUB	61049
Product familv PearlFit			
1112	PearlFit Roll 40	764017806PearlFitH4	61131
1113	PearlFit Roll 50	764017806PearlFitH4	61131
1114	PearlFit Cushion 30x20x4	764017806PearlFitH4	61131
1115	PearlFit Cushion 50x30x7	764017806PearlFitH4	61131
1116	PearlFit Cushion 50x30x10	764017806PearlFitH4	61131
1117	PearlFit Wedge 26x25x7	764017806PearlFitH4	61131
1118	PearlFit Flex 6	764017806PearlFitH4	61131
1119	PearlFit Flex 3	764017806PearlFitH4	61131
1120	PearlFit Cushion 130x60x10	764017806PearlFitH4	61131
1121	PearlFit Head/Neck	764017806PearlFitH4	61131
1122	PearlFit Forehead	764017806PearlFitH4	61131

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1123	PearlFit Inlav Head	764017806PearlFitH4	61131
1124	PearlFit Cushion 50x20x4	764017806PearlFitH4	61131
1132	PearlFit Wedge 56x50x25	764017806PearlFitH4	61131
1136	PearlFit Cushion 22x8x1	764017806PearlFitH4	61131
1137	PearlFit Cushion 30x11x2	764017806PearlFitH4	61131
1138	PearlFit Wedge 30x50x15	764017806PearlFitH4	61131
1140	PearlFit Cushion 200x75x7	764017806PearlFitH4	61131
1142	PearlFit Cushion 50x50x5	764017806PearlFitH4	61131
1145	PearlFit Cushion 27x6x1	764017806PearlFitH4	61131
1148	PearlFit Head/Neck Tilt15	764017806PearlFitH4	61131
1179	PearlFit Cushion DIM	764017806PearlFitH4	61131
1180	PearlFit Wedge DIM	764017806PearlFitH4	61131
1191	PearlFit Wedge 56x50x25 blue	764017806PearlFitH4	61131
5005	PearlFit Forehead Kit	764017806PearlFitFHKitG2	61131
Product familv PearlFitVac			
1125	PearlFit Cushion 30x20x4 Vac	764017806PearlFitVac4N	61131
1126	PearlFit Cushion 50x30x7 Vac	764017806PearlFitVac4N	61131
1127	PearlFit Cushion 50x30x10 Vac	764017806PearlFitVac4N	61131
1128	PearlFit Wedge 26x25x7 Vac	764017806PearlFitVac4N	61131
1129	PearlFit Cushion 130x50x10 Vac	764017806PearlFitVac4N	61131
1130	PearlFit Head/Neck Vac	764017806PearlFitVac4N	61131
1131	PearlFit Cushion 50x20x4 Vac	764017806PearlFitVac4N	61131
1133	PearlFit Wedge 56x50x25 Vac	764017806PearlFitVac4N	61131
1139	PearlFit Wedge 30x50x15 Vac	764017806PearlFitVac4N	61131
1141	PearlFit Cushion 200x75x7 Vac	764017806PearlFitVac4N	61131
1143	PearlFit Cushion 50x50x5 Vac	764017806PearlFitVac4N	61131
1144	PearlFit Cushion 90x60x5 Vac	764017806PearlFitVac4N	61131
1146	PearlFit Cushion MAQSIE Vac	764017806PearlFitVac4N	61131
1147	PearlFit Vac Adapter	764017806PearlFitVac4N	61131
1186	PearlFit Wedge 56x50x25 NUC Vac	764017806PearlFitVac4N	61131
1188	PearlFit Cushion 50x30x5 Vac	764017806PearlFitVac4N	61131
1189	PearlFit Cushion 130x60x5 Vac	764017806PearlFitVac4N	61131
1190	PearlFit Cushion 200x75x5 Vac	764017806PearlFitVac4N	61131
Product familv ProFoam			
1150	ProFoam Plate 25x18x5	764017806ProFoamTH	61131
1151	ProFoam Wedge 18x25x12	764017806ProFoamTH	61131
1152	ProFoam Wedge 26x25x7	764017806ProFoamTH	61131
1153	ProFoam Wedge 18x11x5	764017806ProFoamTH	61131
1154	ProFoam Wedge 36x25x12	764017806ProFoamTH	61131
1155	ProFoam Wedge 60x25x12	764017806ProFoamTH	61131
1156	ProFoam Plate 32x32x10 DS	764017806ProFoamTH	61131
1157	ProFoam Plate 32x32x5 DS	764017806ProFoamTH	61131
1158	ProFoam Plate 25x18x5 DS	764017806ProFoamTH	61131
1159	ProFoam Wedge 18x25x12 DS	764017806ProFoamTH	61131
1160	ProFoam Wedge 26x25x7 DS	764017806ProFoamTH	61131
1161	ProFoam Wedge 18x11x5 DS	764017806ProFoamTH	61131
1162	ProFoam Wedge 36x25x12 DS	764017806ProFoamTH	61131
1163	ProFoam Wedge60x25x12 DS	764017806ProFoamTH	61131
1181	ProFoam Plate DIM	764017806ProFoamTH	61131
1182	ProFoam Wedge DIM	764017806ProFoamTH	61131
1192	ProFoam Plate 50x30x20 DS	764017806ProFoamTH	61131
1193	PoFoam Wedge 50x25x12	764017806ProFoamTH	61131
1194	PoFoam Wedge 50x25x12 DS	764017806ProFoamTH	61131
1195	PoFoam Wedge 18x25x7	764017806ProFoamTH	61131

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1196	PoFoam Wedge 18x25x7 DS	764017806ProFoamTH	61131
1197	PoFoam Wedge 18x23x10 30°	764017806ProFoamTH	61131
1198	PoFoam Wedge 18x23x10 30° DS	764017806ProFoamTH	61131
1199	ProFoam Table Mat 200x55x3 DS	764017806ProFoamTH	61131
1200	ProFoam Table Mat 180x50x3 DS	764017806ProFoamTH	61131
1201	ProFoam Table Mat 200x55x3 DSR	764017806ProFoamTH	61131
1202	ProFoam Table Mat 180x50x3 DSR	764017806ProFoamTH	61131
1245	ProFoam Head	764017806ProFoamTH	61131
1246	ProFoam Head/Neck	764017806ProFoamTH	61131
1247	ProFoam Plate 50x25x1 DSR	764017806ProFoamTH	61131
1248	ProFoam Plate 100x25x1 DSR	764017806ProFoamTH	61131
1249	ProFoam Table Mat 200x60x3 DSRG	764017806ProFoamTH	61131
1250	ProFoam Table Mat 200x60x3 DSG	764017806ProFoamTH	61131
1251	ProFoam Table Mat 200x70x3 DSRG	764017806ProFoamTH	61131
1252	ProFoam Table Mat 200x70x3 DSG	764017806ProFoamTH	61131
1253	ProFoam Table Mat 200x60x5 MFG	764017806ProFoamTH	61131
1254	ProFoam Table Mat 200x60x3 DSRGP	764017806ProFoamTH	61131
1255	ProFoam Table Mat 200x60x3 DSGP	764017806ProFoamTH	61131
1256	ProFoam Table Mat 200x70x3 DSRGP	764017806ProFoamTH	61131
1257	ProFoam Table Mat 200x70x3 DSGP	764017806ProFoamTH	61131
1258	ProFoam Table Mat 200x60x5 MFGP	764017806ProFoamTH	61131
1273	ProFoam Wedge Inclination 15	764017806ProFoamTH	61131
1274	ProFoam Wedge Inclination 30	764017806ProFoamTH	61131
1275	ProFoam Wedge Inclination 40	764017806ProFoamTH	61131
1279	ProFoam Head Support	764017806ProFoamTH	61131
1282	ProFoam Table Mat 240x60x3	764017806ProFoamTH	61131
1283	ProFoam Table Mat 240x60x3 DSG	764017806ProFoamTH	61131
1284	ProFoam Table Mat 240x70x3	764017806ProFoamTH	61131
1285	ProFoam Table Mat 240x70x3 DSG	764017806ProFoamTH	61131
1287	ProFoam Table Mat 200x70x3 DSR	764017806ProFoamTH	61131
1289	ProFoam Table Mat 90x45x1 DSRG	764017806ProFoamTH	61131
5018	ProFoam Wedge Inclination Kit	764017806ProFoamTH	61131
Product family CT Table Cover			
1164	CT Table Cover 2090	764017806CTTableCoverFK	61131
1165	CT Table Cover 1790	764017806CTTableCoverFK	61131
1166	CT Table Cover 2360	764017806CTTableCoverFK	61131
1167	CT Table Cover 1860	764017806CTTableCoverFK	61131
1168	CT Table Cover 2070	764017806CTTableCoverFK	61131
1169	CT Table Cover 400	764017806CTTableCoverFK	61131
1175	CT Table Cover 310	764017806CTTableCoverFK	61131
1177	CT Table Cover 2190 S	764017806CTTableCoverFK	61131
1183	CT Table Cover 2220 P	764017806CTTableCoverFK	61131
1203	CT Table Cover 2320 P44	764017806CTTableCoverFK	61131
1204	CT Table Cover 2100 P	764017806CTTableCoverFK	61131
1184	CT Table Cover 2170 G	764017806CTTableCoverFK	61131
1185	CT Table Cover 270 G	764017806CTTableCoverFK	61131
1205	CT Table Cover 2720 G	764017806CTTableCoverFK	61131
1206	CT Table Cover 2580 G	764017806CTTableCoverFK	61131
1207	CT Table Cover 2100 G	764017806CTTableCoverFK	61131
1208	CT Table Cover 370 G	764017806CTTableCoverFK	61131
1209	CT Table Cover 2400 S	764017806CTTableCoverFK	61131
1210	CT Table Cover 350 S	764017806CTTableCoverFK	61131
1211	CT Table Cover 2170 S46	764017806CTTableCoverFK	61131
1212	CT Table Cover 2190 S46	764017806CTTableCoverFK	61131

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1221	CT Table Cover 2630 G	764017806CTTableCoverFK	61131
1223	CT Table Cover 2400 S46	764017806CTTableCoverFK	61131
1224	CT Table Cover 2450 P	764017806CTTableCoverFK	61131
1239	CT Table Cover 2580 P44	764017806CTTableCoverFK	61131
1244	CT Table Cover 2700 P44	764017806CTTableCoverFK	61131
1267	CT Table Cover 2050 G	764017806CTTableCoverFK	61131
1280	CT Table Cover 170	764017806CTTableCoverFK	61131
1281	CT Table Cover 200	764017806CTTableCoverFK	61131
1290	CT Table Cover 2140 P	764017806CTTableCoverFK	61131
1291	CT Table Cover 1985 SV	764017806CTTableCoverFK	61131
Product familv ProBelt			
1170	ProBelt 200 R2	764017806ProBeltSJ	61131
1171	ProBelt 200 R3	764017806ProBeltSJ	61131
1172	ProBelt 200 T5	764017806ProBeltSJ	61131
1173	ProBelt 200 Thorax PFC	764017806ProBeltThorax5E	61131
1174	ProBelt 200 Thorax PFW	764017806ProBeltThorax5E	61131
1213	ProBelt 200 Extension	764017806ProBeltSJ	61131
1187	ProBelt 200 Wrap	764017806ProBeltSJ	61131
1214	ProBelt 350 R2	764017806ProBeltSJ	61131
1215	ProBelt 350 R3	764017806ProBeltSJ	61131
1216	ProBelt 350 T5	764017806ProBeltSJ	61131
1217	ProBelt 350 Extension	764017806ProBeltSJ	61131
1218	ProBelt 50 VL	764017806ProBeltSJ	61131
1219	ProBelt 140 MRI P	764017806ProBeltSJ	61131
1220	ProBelt 70 Wrap	764017806ProBeltSJ	61131
1222	ProBelt 50 VH	764017806ProBeltSJ	61131
1229	ProBelt 350 Wrap	764017806ProBeltSJ	61131
5008	ProBelt 50VL Kit	764017806ProBeltSJ	61131
5009	ProBelt 50VH Kit	764017806ProBeltSJ	61131
1242	ProBelt 350 J10	764017806ProBeltSJ	61131
1241	ProBelt 200 J10	764017806ProBeltSJ	61131
1240	ProBelt 140 MRI P Extension	764017806ProBeltSJ	61131
5012	ProBelt 50 VL C KIT	764017806ProBeltSJ	61131
1230	ProBelt 50 VL C	764017806ProBeltSJ	61131
1259	ProBelt 200 U5	764017806ProBeltSJ	61131
1260	ProBelt 350 U5	764017806ProBeltSJ	61131
1278	ProBelt 100 T5 V	764017806ProBeltSJ	61131
1286	ProBelt 200 R3 H	764017806ProBeltSJ	61131
Product familv FoamFit			
1225	FoamFit Wedge 18x11x5	764017806FoamFitK6	61131
1226	FoamFit Wedge 36x11x5	764017806FoamFitK6	61131
1227	FoamFit Plate 13x8x2	764017806FoamFitK6	61131
1228	FoamFit Plate 36x8x2	764017806FoamFitK6	61131
1233	FoamFit Plate 28x18x1	764017806FoamFitK6	61131
1234	FoamFit Wedge 5x16x7	764017806FoamFitK6	61131
1235	FoamFit Plate 30x10x2	764017806FoamFitK6	61131
1236	FoamFit Plate 18x8x2	764017806FoamFitK6	61131
1237	FoamFit Plate DIM	764017806FoamFitK6	61131
1238	FoamFit Wedge DIM	764017806FoamFitK6	61131
Product familv Beinhaltergerät			
DB000063	Beinhaltergerät 00	764017806Beinhqeraet4A	61131
DB000064	Positionierbolzen 02	764017806Beinhqeraet4A	61131
DB000137	Beinhaltergerät 03 Oberteil	764017806Beinhqeraet4A	61131
DB000065	Beinhaltergerät 04 Unterteil	764017806Beinhqeraet4A	61131

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Product family Foam			
000031	SieRep Platte 01 B	764017806FoamP2	61131
000032	SieRep Keil 02 B	764017806FoamP2	61131
000033	SieRep Keil 03 B	764017806FoamP2	61131
000034	SieRep Keil 04 B	764017806FoamP2	61131
000035	SieRep Keil 05 B	764017806FoamP2	61131
000036	SieRep Keil 06 B	764017806FoamP2	61131
000037	SieRep Rolle 07 B	764017806FoamP2	61131
000039	SieRep Rolle 09 B	764017806FoamP2	61131
000045	SieRep Schädelform 12 B	764017806FoamP2	61131
000226	SieRep Halbrolle 20 B	764017806FoamP2	61131
000281	SieRep Schädelform 16 B	764017806FoamP2	61131
000367	SieRep Keil 02 A	764017806FoamP2	61131
000368	SieRep Keil 04 A	764017806FoamP2	61131
000369	SieRep Keil 05 A	764017806FoamP2	61131
000370	SieRep Keil 06 A	764017806FoamP2	61131
000371	SieRep Rolle 08 A	764017806FoamP2	61131
000372	SieRep Platte 01 A	764017806FoamP2	61131
000373	SieRep Keil 03 A	764017806FoamP2	61131
000374	SieRep Rolle 07 A	764017806FoamP2	61131
000375	SieRep Rolle 09 A	764017806FoamP2	61131
000376	SieRep Halbrolle 19 A	764017806FoamP2	61131
000377	SieRep Halbrolle 20 A	764017806FoamP2	61131
000207	SieRep Halbrolle 19 B	764017806FoamP2	61131
000227	SieRep Halbrolle 21 B	764017806FoamP2	61131
000750	SieRep Halbrolle 121 B	764017806FoamP2	61131
000482	SieRep Gesichtsform 60 A	764017806FoamP2	61131
Product family Sandbag			
1261	Sandbag 40x20, 3kg	764017806SandbagQW	61131
1262	Sandbag 30x20, 2kg	764017806SandbagQW	61131
1263	Sandbag 24x18, 1.25kg	764017806SandbagQW	61131
Product family Positioning Kits			
5013	Positioning KIT IS Advanced	764017806KITM9	61131
5014	Positioning KIT IS Basic	764017806KITM9	61131
5015	Positioning KIT HP Advanced	764017806KITM9	61131
5016	Positioning KIT DXR Basic	764017806KITM9	61131
5017	Positioning KIT DXR Advanced	764017806KITM9	61131