



## DECLARATION OF CONFORMITY

According to **REGULATION (EU) 2017/745**.

**Manufacturer:**

Company name: Klarity Medical & Equipment  
(GZ) Co., Ltd.  
Address: No. 14, 3rd Street Shawan, GETDD,  
Guangzhou  
Tel: + 86 20 8222 6380  
E-mail: [info@klarity-medical.com](mailto:info@klarity-medical.com)  
SRN: CN-MF-000002229

**Whose Authorized Representative:**

Name: Lotus NL B.V.  
Address: Koningin Julianaplein 10,1e  
Verd, 2595AA, The Hague, Netherlands.  
E-mail: [peter@lotusnl.com](mailto:peter@lotusnl.com)  
SRN: NL-AR-000000121

We, the manufacturer, herewith declare that the device covered by the present EU declaration is in conformity with the (EU) MDR 2017/745.

<b>Product Name</b>	Orthotic splint		
<b>Model</b>	see attachment		
<b>Intend use</b>	Orthotic splint is for fabrication of custom-molded splints, orthoses and adaptive equipment.		
<b>EMDN code</b>	L09	<b>Basic UDI-DI</b>	692082412026CL
<b>Classification and rule</b>	I, rule1	<b>Conformity Assessment Route</b>	Article 19, Annex II and Annex III

**Applicable Standards and CS:**

EN ISO 13485:2016  
ISO 10993-1:2018

ISO 14971:2019  
EN 1041:2008

EN 62366-1:2015  
EN 15223-1:2016

We, the manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the REGULATION (EU) 2017/745. We agree to develop, implement and maintain a documented post-production monitoring process.

**Signed:**

**Name of authorized signatory: Guohuang Zhou**

**Date:** June 28, 2024

**Position held in the company:** Management Representative

**Place:** Guangdong , China

Klarity Medical & Equipment (GZ) Co., Ltd.

**Attachment**

<b>Serial number</b>	<b>Model</b>	<b>Serial number</b>	<b>Model</b>
1	CB-2400A	41	CP-2401A
2	CB-2400AK	42	CP-2401B
3	CB-2400B	43	CP-3200
4	CB-2401A	44	CP-3200A
5	CB-2401B	45	CP-3200K
6	CB-3200	46	CP-3201
7	CB-3200A	47	CP-3201A
8	CB-3200K	48	CPB-2400A
9	CB-3201	49	CPB-2400AK
10	CB-3201A	50	CPB-2401A
11	CB-3205A	51	CPB-3200
12	CB-3219A	52	CPB-3200A
13	CBL-3200	53	CPB-3200K
14	CBL-3200A	54	CPB-3201
15	CBL-3200B	55	CPB-3201A
16	CBL-3200K	56	EZ-2400A
17	CBL-3201	57	EZ-2400AK
18	CBL-3201A	58	EZ-2401A
19	CBL-3201B	59	EZ-3200
20	CBR-3200	60	EZ-3200A
21	CBR-3200A	61	EZ-3200K
22	CBR-3200B	62	EZ-3201
23	CBR-3200K	63	EZ-3201A
24	CBR-3201	64	EZS-3200
25	CBR-3201A	65	EZS-3200A
26	CBR-3201B	66	EZS-3200K
27	CBW-2400A	67	EZS-3201
28	CBW-2400B	68	EZS-3201A
29	CBW-2401A	69	KBS-3200
30	CBW-2401B	70	KBS-3200A
31	CBW-3200	71	KBS-3200K
32	CBW-3200A	72	KBS-3201
33	CBW-3200B	73	KBS-3201A
34	CBW-3200K	74	P-3200AT
35	CBW-3201	75	KBS-3202
36	CBW-3201A	76	KBS-3202A
37	CBW-3201B	77	KBS-3205
38	CP-2400A	78	KBS-3205A
39	CP-2400AK	79	KS-2400A
40	CP-2400B	80	KS-2401A

Serial number	Model	Serial number	Model
81	KS-2419	121	P1-2436A
82	KS-2419A	122	P1-3200
83	KS-3200	123	P1-3200A
84	KS-3200A	124	P1-3200AT
85	KS-3200B	125	P1-3201
86	KS-3200K	126	P1-3201A
87	KS-3201	127	P1-3201AT
88	KS-3201A	128	P1-3205
89	KS-3201B	129	P1-3205A
90	KS-3201D	130	P1-3219
91	KS-3205	131	P1-3219A
92	KS-3205A	132	P1-3242
93	KS-3219	133	P1-3242A
94	KS-3219A	134	P1-4000A
95	KSP-3200	135	P1-4001A
96	KSP-3200A	136	P-1600
97	KSP-3200AK	137	P-1600A
98	KSP-3200K	138	P-1600B
99	KSP-3201	139	P-1600BK
100	KSP-3201A	140	P-1600K
101	KSP-3205	141	P-1611
102	KSR-3219	142	P-1611A
103	KSR-3219A	143	P-1611B
104	P1-1600	144	P-1612
105	P1-1600A	145	P-1612A
106	P1-1611	146	P-1622
107	P1-1611A	147	P-1636
108	P1-1612	148	P-1636A
109	P1-1612A	149	P-1636AC
110	P1-1636	150	P-2000
111	P1-1636A	151	P-2000A
112	P1-2000	152	P-2000K
113	P1-2000A	153	P-2001
114	P1-2400	154	P-2001A
115	P1-2400A	155	P-2001K
116	P1-2411A	156	P-2011A
117	P1-2412	157	P-2012
118	P1-2412A	158	P-2012A
119	P1-2415A	159	P-2015A
120	P1-2436	160	P-2019

Serial number	Model	Serial number	Model
161	P-2019A	201	P2-3242
162	P-2022	202	P2-3242A
163	P-2036	203	P-2400
164	P2-1600	204	P2-4000
165	P2-1600A	205	P2-4000A
166	P2-1611	206	P2-4001
167	P2-1611A	207	P-2400-343
168	P2-1612	208	P-2400A
169	P2-1612A	209	P-2400AK
170	P2-1636	210	P-2400B
171	P2-1636A	211	P-2400K
172	P2-2000	212	P-2400T
173	P2-2000A	213	P-2400T2
174	P2-2000K	214	P-2400TK
175	P2-2001A	215	P-2401
176	P2-2005A	216	P-2401A
177	P2-2011	217	P-2405
178	P2-2011A	218	P-2405A
179	P2-2012A	219	P-2411
180	P2-2019	220	P-2411A
181	P2-2019A	221	P-2412
182	P2-2400	222	P-2412A
183	P2-2400A	223	P-2415
184	P2-2401A	224	P-2415A
185	P2-2405A	225	P-2415B
186	P2-2411A	226	P-2422
187	P2-2412	227	P-2436
188	P2-2412A	228	P-2436-343
189	P2-2415A	229	P-2436A
190	P2-2436	230	P-2436AT
191	P2-2436A	231	P-2436B
192	P2-3200	232	P-2436T
193	P2-3200A	233	P-2436T2
194	P2-3200AT	234	P-2436T3
195	P2-3201	235	P-3200
196	P2-3201A	236	P-3200A
197	P2-3201AT	237	P-3200B
198	P2-3205	238	P-3200K
199	P2-3205A	239	P-3200T
200	P2-3219A	240	P-3200T3

Serial number	Model	Serial number	Model
241	P-3200TK	281	PB1-1612A
242	P-3201	282	PB1-2412A
243	P-3201A	283	PB-1600
244	P-3201AT	284	PB-1600A
245	P-3201B	285	PB-1600K
246	P-3201T	286	PB-1611A
247	P-3205	287	PB-1612
248	P-3205A	288	PB-1612A
249	P-3205S	289	PB-2400
250	P-3219	290	PB-2400A
251	P-3219A	291	PB-2400K
252	P-3219B	292	PB-2412
253	P-3242	293	PB-2412A
254	P-3242A	294	PB-2415
255	P-3242AT	295	PB-3200
256	P-3242B	296	PB-3200A
257	P-3242T	297	PB-3200K
258	P-3242T3	298	PB-3201
259	P-4000	299	PB-3201A
260	P-4000A	300	PB-3205
261	P-4000K	301	PB-3205A
262	P-4001	302	PB-3219
263	P-4001A	303	PB-3219A
264	P-4001K	304	PC1-2412A
265	P-4005	305	PC1-3219A
266	P-4005A	306	PC-1600
267	P-4005K	307	PC-1600A
268	P-4005S	308	PC-1600K
269	P-4005SK	309	PC-1611
270	P5-1600	310	PC-1611A
271	P5-1600A	311	PC-1612
272	P5-2412	312	PC-1612A
273	P5-2412A	313	PC2-2412A
274	P5-3200	314	PC2-3201A
275	P5-3200A	315	PC-2400
276	P5-4000	316	PC-2400A
277	P5-4000A	317	PC-2400K
278	P5-4001A	318	PC-2412
279	P6-3200	319	PC-2412A
280	P6-4000	320	PC-2415

Serial number	Model	Serial number	Model
321	PC-2415A	361	PS-1600BK
322	PC-3200	362	PS-1600K
323	PC-3200A	363	PS-1611
324	PC-3200K	364	PS-1611A
325	PC-3201	365	PS-1611B
326	PC-3201A	366	PS-1612
327	PC-3205	367	PS-1612A
328	PC-3205A	368	PS-1636
329	PC-3219	369	PS-1636A
330	PC-3219A	370	PS-2000
331	PRB-3200	371	PS-2000A
332	PRB-3200A	372	PS-2000B
333	PRB-3200K	373	PS-2000K
334	PRB-3201	374	PS-2011
335	PRB-3201A	375	PS-2011A
336	PRB-3205	376	PS-2012
337	PRB-3205A	377	PS-2012A
338	PRR-2412A	378	PS-2015
339	PRR-3200	379	PS-2015A
340	PRR-3200A	380	PS-2015B
341	PRR-3200K	381	PS-2022
342	PRR-3201	382	PS-2022A
343	PRR-3201A	383	PS2-1600A
344	PRR-3205	384	PS2-1600B
345	PRR-3205A	385	PS2-1611A
346	PRY-3200	386	PS2-1611B
347	PRY-3200A	387	PS2-1612
348	PRY-3200K	388	PS2-1612A
349	PRY-3201	389	PS2-2000A
350	PRY-3201A	390	PS2-2011A
351	PRY-3205A	391	PS2-2022
352	PS1-1611A	392	PS2-2022A
353	PS1-2011A	393	PS2-2400
354	PS1-2415A	394	PS2-2400A
355	PS1-3201A	395	PS2-2400B
356	PS1-3205A	396	PS2-2412
357	PS1-3219A	397	PS2-2412A
358	PS-1600	398	PS2-2415A
359	PS-1600A	399	PS2-2415B
360	PS-1600B	400	PS2-3200

Serial number	Model	Serial number	Model
401	PS2-3200A	441	PV-1612A
402	PS2-3200AT	442	PV-2400
403	PS2-3200B	443	PV-2400A
404	PS2-3201	444	PV-2400K
405	PS2-3201A	445	PV-2412
406	PS2-3205	446	PV-2412A
407	PS2-3205A	447	PV-2415
408	PS2-3219	448	PV-3200
409	PS2-3219A	449	PV-3200A
410	PS2-3219B	450	PV-3200K
411	PS-2400	451	PV-3201
412	PS-2400A	452	PV-3201A
413	PS-2400K	453	PV-3205A
414	PS-2401	454	PV-3219
415	PS-2401A	455	PV-3219A
416	PS-2412	456	PVBG-1636A
417	PS-241250	457	PVBG-1636B
418	PS-2412A	458	PVBG-2436A
419	PS-2415	459	PVBG-2436B
420	PS-2415A	460	PVBG-3201A
421	PS-2415A1515	461	PVBG-3201B
422	PS-2415B	462	PVBG-3205A
423	PS-3200	463	PVBG-3205B
424	PS-3200A	464	PVS-1636A
425	PS-3200AT	465	PVS-1636B
426	PS-3200B	466	PVS-2436A
427	PS-3200K	467	PVS-2436B
428	PS-3200T	468	PVS-3201A
429	PS-3200TK	469	PVS-3201B
430	PS-3201	470	PVS-3205A
431	PS-3201A	471	PVV-4000A
432	PS-3201AT	472	PVV-4001A
433	PS-3201T	473	SPB-2400
434	PS-3205	474	SPB-2400A
435	PS-3205A	475	SPB-2400K
436	PS-3219	476	SPB-2419
437	PS-3219A	477	SPB-3200
438	PV-1600A	478	SPB-3200A
439	PV-1611A	479	SPB-3200K
440	PV-1612	480	SPB-3219

Serial number	Model	Serial number	Model
481	SPC-2400	521	SPP-3219A
482	SPC-2400A	522	SPP-3219
483	SPC-2400K	523	SPVBG-3201A
484	SPC-3200	524	SPVBG-3201
485	SPC-3200A	525	SPVBG-3205A
486	SPC-3200K	526	SPVBG-3205
487	SPVBG-2419A	527	SPVBG-3219A
488	SPVBG-3200A	528	SPVBG-3219
489	A401-1KS	529	PSF-2400
490	A401-2KS	530	PSF-2400A
491	A401-3KS	531	PSF-2405
492	A401-4KS	532	PSF-2405A
493	SPW-2400	533	PSF-3200
494	SPW-2400A	534	PSF-3200A
495	SPW-2400K	535	PSF-3205
496	SPW-2401	536	PSF-3205A
497	SPW-2419	537	PBF-2400
498	SPW-2419A	538	PBF-2400A
499	A401-5KS	539	PBF-2405
500	A401-6KS	540	PBF-2405A
501	SPW-3200K	541	PBF-3200
502	A402-1KS	542	PBF-3200A
503	A402-2KS	543	PBF-3205
504	SPW-3205	544	PBF-3205A
505	SPW-3205A	545	PF-4000
506	SPW-3219	546	PF-4000A
507	SPW-3219A	547	PF-4005
508	PY-3200A	548	PF-4005A
509	PY-3201A	549	A201-KSL
510	P-RB01	550	A201-KSM
511	SPW-1600A	551	A201-KSS
512	SPW-1619A	552	A202-3200CPL
513	SPW-3200	553	A202-3200CPM
514	SPW-3201	554	A202-3200CPS
515	SPW-3200A	555	A202-KBSLO
516	SPW-3201A	556	A202-KSL
517	SPP-3200	557	A202-KSM
518	SPP-3201	558	A202-KSS
519	SPP-3200A	559	A203-KSM
520	SPP-3201A	560	A204-KBSMO

<b>Serial number</b>	<b>Model</b>	<b>Serial number</b>	<b>Model</b>
561	A204-KSM	601	B601-KSM
562	A205-KSL	602	B601-KSS
563	A205-KSM	603	KV-B6010
564	A205-KSS	604	KV-B6011
565	A206-KSL	605	KV-B6012
566	A206-KSM	606	KV-B6013
567	A206-KSS	607	C301-KSL
568	A207-KSL	608	C301-KSM
569	A207-KSM	609	C301-KSS
570	A207-KSS	610	C302-KSL
571	A209-KBSMO	611	C302-KSM
572	A209-KSL	612	C302-KSS
573	A209-KSM	613	L203-KBSL
574	A209-KSS	614	L203-KBSM
575	A210-KSL	615	L203-KBSS
576	A210-KSM	616	L203-KSL
577	A210-KSS	617	L203-KSM
578	A211-KSL	618	L203-KSS
579	A211-KSM	619	L203-PS
580	A211-KSS	620	L204-KBSL
581	A212-KBSMO	621	L204-KBSLO
582	A212-KBSSO	622	L204-KBSM
583	A212-KSL	623	L204-KBSS
584	A212-KSM	624	L204-KBSSO
585	A212-KSS	625	L204-KSL
586	A212-PS	626	L204-KSM
587	A213-KBSMO	627	L204-KSS
588	A213-KBSSO	628	L204-KSXL
589	A213-KSL	629	L205-KBSL
590	A213-KSM	630	L205-KBSM
591	A213-KSS	631	L205-KBSS
592	A214-KSL	632	L205-KSL
593	A214-KSM	633	L205-KSL3205
594	A214-KSS	634	L205-KSM
595	A219-KBSMO	635	L205-KSM3205
596	A219-KSL	636	L205-KSS
597	A219-KSM	637	L205-KSS3205
598	A219-KSS	638	L206-KBSL
599	B601F-KSM	639	L206-KBSM
600	B601-KSL	640	L206-KBSMO

Serial number	Model	Serial number	Model
641	L206-KBSS	681	KSPC-11515
642	L206-KBSSO	682	KSPC-6020
643	L206-KSL	683	KSPC-7520
644	L206-KSL3205	684	KSPC-10020
645	L206-KSM	685	KSPC-11520
646	L206-KSM3205	686	KSPC-6030
647	L206-KSS	687	KSPC-7530
648	L206-KSS3205	688	KSPC-10030
649	L207-KBSL	689	KSPC-11530
650	L207-KBSM	690	KSPC-9020
651	L207-KBSMO	691	JM-1611NLJ
652	L207-KBSS	692	JM-1611NMJ
653	L207-KSL	693	JM-1611NSJ
654	L207-KSL3205	694	JM1-P1611
655	L207-KSM	695	JM1-PS1611
656	L207-KSM3205	696	JM-2G
657	L207-KSS	697	JM-A
658	L207-KSS3205	698	JM-B
659	PB-1600C	699	JM-C
660	KSPC-3007	700	JM-D
661	KSPC-4007	701	JM-E
662	KSPC-5007	702	JM-F
663	KSPC-3010	703	JM-FJ
664	KSPC-4010	704	JM-G
665	KSPC-5010	705	JM-S1
666	KSPC-6010	706	JM-S2
667	KSPC-7510	707	JM-S3
668	KSPC-3012	708	JM-PS1611NM
669	KSPC-4012	709	PBF-2405 Klarity Pro
670	KSPC-5012	710	PBF-2412 Klarity Pro
671	KSPC-6012	711	PRYF-2405 Klarity Pro
672	KSPC-7512	712	PSF-2405 Klarity Pro
673	KSPC-10012	713	PSF-2412 Klarity Pro
674	KSPC-11512	714	PBF-3205 Klarity Pro
675	KSPC-3015	715	PSF-3205 Klarity Pro
676	KSPC-4015	716	PF-4005 Klarity Pro
677	KSPC-5015	717	PBF-4005 Klarity Pro
678	KSPC-6015	718	02010007
679	KSPC-7515	719	02010008
680	KSPC-10015	720	02010021

Serial number	Model	Serial number	Model
721	02010022	761	02010047
722	02010023	762	02010048
723	02010018	763	02010049
724	02010019	764	02010050
725	02010020	765	02010051
726	02010004	766	02010052
727	02010005	767	02010053
728	02010006	768	02010054
729	02010009	769	02010055
730	02010010	770	02010056
731	02010011	771	02010057
732	02010012	772	02010058
733	02010013	773	02010059
734	02010014	774	2130001
735	02010015	775	2130002
736	02010016	776	2130003
737	02010017	777	2130004
738	02010024	778	2130005
739	02010025	779	2130006
740	02010026	780	2130007
741	02010027	781	2130008
742	02010028	782	2130009
743	02010029	783	2130010
744	02010030	784	2130011
745	02010031	785	2130012
746	02010032	786	2130013
747	02010001	787	2130014
748	02010002	788	2130015
749	02010003	789	2130016
750	02010036	790	2130017
751	02010037	791	2130018
752	02010038	792	2130021
753	02010039	793	2130022
754	02010040	794	2130023
755	02010041	795	2130024
756	02010042	796	KG-A02
757	02010043	797	KG-A02CP
758	02010044	798	KG-A03
759	02010045	799	KG-A03CP
760	02010046	800	KG-B02

Serial number	Model	Serial number	Model
801	FZ-1401	841	FZA-2325AJ
802	FZ-1402	842	FZA-2325A
803	FZA-50CJ	843	FZA-2338B
804	FZA-510RJ	844	FAZ-2338AJ
805	FZ-1302	845	FZA-2338A
806	FZ-1303	846	FZA-2350B
807	FZVBS-3830	847	FZA-2350AJ
808	FZVBS-3860	848	FZW-2325B
809	FZ-1003	849	FZW-2325AJ
810	FZ-1006	850	FZW-2338B
811	A402-4KS	851	FZW-2338AJ
812	A402-5KS	852	FZL-38AC
813	A402-6KS	853	FZL-8038AJR
814	A405-1KS	854	FZ-1025
815	A405-2KS	855	FZ-1038
816	A405-3KS	856	FZ-1825
817	A405-4KS	857	FZ-2203-1
818	A405-5KS	858	FZ-2201
819	A405-6KS	859	FZ-2019-1
820	L3011-KSL	860	FZ-2019-2
821	L3021-KSS	861	FZ-2019-3
822	KA504-15	862	FZ-2015
823	KA504-16	863	FZ-2016
824	KA504-17	864	FZ-2018
825	KA501	865	FZ-2019
826	FZ-1601	866	FZ-2020
827	FZ-1602	867	FZ-2021
828	FZ-1603	868	FZ-2022
829	FZ-1304	869	FZ-2101
830	FZ-2325L25	870	FZ-2102
831	FZ-2338L38	871	FZ-2103
832	FZ-2325A	872	FZ-2104
833	FZ-2325AJ	873	FZ-1126
834	FZ-2325B	874	KLH-02S
835	FZ-2338A	875	KLH-02L
836	FZ-2338AJ	876	P2-4001A
837	FZ-2338B	877	FZAS-3830
838	FZ-2350B	878	FZAS-3860
839	FZ-2350AJ	879	A402-3KS
840	FZA-2325B	880	PMG-1600A

Serial number	Model	Serial number	Model
881	PMG-1611A	921	
882	PMG-2000A	922	
883	PMG-2011A	923	
884	PMG-2400A	924	
885	PMG-2415A	925	
886	PMG-3200A	926	
887	PMG-3219A	927	
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