

Declaration of Conformity

Name of Manufacturer: Auckland Medical Polymer (Tianjin) Co., Ltd.
Address: Building D5-2, XEDA International Industrial Park, Xiqing Economic Development Area (XEDA), Tianjin, 300385, China.
Tel/Fax: 0086-22-23827978 / 0086-22-23828536
Web: www.okltj.com

European Representative: SUNGO Europe B.V.
Olympisch Stadion 24, 1076DE Amsterdam
Tel/Fax : +31 08 5029 0204

Product : Positioning Pads

Model Code: 1100 group, 2100 group, 3100 group, 4100 group, 5100 group, 6100 group, 7100 group, 8000 group, 8100 group, 9100 group
OKL-T group, OKL-C group, OKL-A group, OKL-B group, OKL-X group, OKL-S group, OKL-K group, OKL-L group, OKL-Z group, OKL-F group, OKL-Y group, OKL-J group, OKL-CW group, OKL-SD group, OKL-M group, OKL-FW group, Accessory
Product list in Table 1 & Table 2.

Classification Class I
(MDR, Annex IX) According to MDR (EU) 2017/745 Annex VIII, Rule 1 of Chapter.

Conformity Routes: Self declaration of conformity as per terms of Regulation (EU) 2017/745 ANNEX IV.

We herewith declare that the above-mentioned products meet the provisions of the following EU Regulation and Standards. All supporting documentations are retained under the premises of the manufacturer.

DIRECTIVES

General applicable directives :

Medical Device Regulation : Regulation (EU) 2017/745 concerning medical devices (MDR 2017/745).

Date : Dec 27, 2021
Place : China / Tianjin

Signature : Jessie Gao
Name/Position : Jessie Gao / VP



Declaration of Conformity

Table 1

Basic UDI-DI code 69534970SSD102V5									
1100 group	1101-1	1101-2	1101-3	1101-4	1101-5	1101-6	1101-7	1101-8	1101-9
	1101-11	1101-12	1101-13	1101-14	1101-15	1101-16	1101-17	1101-18	1102-1
	1102-2	1102-3	1102-4	1102-5	1102-6	1102-7	1102-8	1102-9	1102-10
	1102-11	1103-1	1103-2	1103-3	1103-4	1103-5	1103-6	1103-7	1103-8
	1103-9	1104	1105-1	1105-2	1105-3	1105-4	1105-5	1106-1	1106-2
	1106-3	1106-4	1107-1	1107-2	1107-3	1107-3B	1108-1	1108-2	1109-1
	1109-2	1110-1	1110-2	1110-3	1110-4	1110-5	1110-6	1110-7	1111-0
	1112								
2100 group	2101-1	2101-2	2101-3	2101-4	2102	2103	2103-1	2104	2104-1
	2105-1	2109-1	2109-2						
3100 group	3101-1	3101-2	3101-3	3102-1	3102-3	3102-4	3102-5	3102-6	3102-7
	3102-8	3102-9	3102-10	3102-10A	3102-10B	3102-11	3102-11A	3102-11B	3102-11C
	3102-11D	3103	3103-1	3103-2	3103-3	3103-4	3103-5	3103-6	3103-7
	3104	3104-1	3104-2	3104-3	3104-4	3104-5	3104-6	3104-7	3104-8
	3104-9	3104-10	3104-11	3104-12	3104-13	3104-14	3104-15	3104-16	3104-17
	3104-18	3105	3105-1	3106	3106-1	3106-2	3106-3	3106-4	3106-5
	3106-6	3106-7	3107-1	3107-2	3107-3	3107-4	3107-5	3107-6	3107-9
	3107-10	3107-11	3107-12	3109-1	3109-2	3109-3	3109-4	3109-5	3109-6
	3109-7	3109-8	3109-9	3109-10	3109-11	3109-12	3109-13	3109-14	3109-15
	3109-16								
4100 group	4101-1	4101-2	4101-3	4101-4	4101-5	4101-6	4101-7	4101-8	4101-9
	4101-10	4101-11	4101-12	4101-13	4101-14	4101-15	4101-16	4101-17	4101-21
	4101-22	4101-23	4101-24	4101-25	4101-26	4101-27	4101-28	4101-29	4101-30
	4101-31	4101-32	4101-33	4101-34	4101-35	4101-36	4101-37	4101-38	4101-39
	4101-40	4101-41	4101-42	4102-1	4102-2	4102-3	4102-4	4102-5	4102-6
	4102-7	4102-8	4102-9	4103	4103-1	4103-2	4103-3	4103-4	4103-5
	4104-1	4104-1-A	4104-2	4104-3	4104-4	4104-5	4104-6	4104-7	4104-8
	4104-9	4104-10	4104-11	4104-12	4104-13	4104-14	4104-15	4104-16	4104-17
	4104-18	4104-19	4104-20	4104-21	4104-22	4104-23	4104-24	4104-25	4104-26
	4104-27	4104-28	4105	4105-1	4105-2	DZ4106	4106	4106-1	4106-2
	4107-1	4107-2	4107-3	4107-4	4108	4109-1	4101-18	4101-19	4101-20
5100 group	5101-1	5101-2	5101-3	5101-4	5101-5	5101-8	5101-9	5101-10	5101-11
	5101-12	5101-13	5101-14	5101-15	5101-16	5101-17A	DZ5101-4	DZ5101-5	DZ5101-6
	DZ5101-7	DZ5101-8	5101-17B	5101-18	5201-1	5201-2	5201-3	5201-4	5201-5
	5201-6	5301-1							
6100 group	6101-1	6101-1-A	6101-1-B	6101-1-C	6101-1-D	6101-2	6101-3	6101-4	
7100 group	7101-1	7101-2	7101-3	7101-4	7101-5	7101-6	7101-7	7101-8	
								7101-9	

Declaration of Conformity

	7101-10	7101-11	7101-12						
8000 group	8013-1	8013-2	8013-3	8013-4	8013-5	8013-6	8021-1	8021-2	8021-3
	8022-1	8022-2	8022-3	8023-1	8023-2	8023-3	8023-4	8023-5	8023-6
	8023-7	8023-8	8023-9	8023-10	8023-11	8031-1	8031-2	8031-3	8041-1
	8041-2	8041-3	8041-4						
8100 group	8101-1	8101-2	8101-3						
9100 group	9102-1	9102-3	9102-3B	9102-4	9104-1				
Accessory	RP01								

Table 2

Basic UDI-DI code 69534970YSD105XR									
OKL-FW	OKL-FW01	OKL-FW02	OKL-FW03	OKL-FW04	OKL-FW05	OKL-FW06	OKL-FW07	OKL-FW08	
OKL-CW	OKL-CW01	OKL-CW02	OKL-CW03	OKL-CW04	OKL-CW05	OKL-CW06	OKL-CW07		
OKL-T	OKL-T01	OKL-T02	OKL-T03	OKL-T04	OKL-T05	OKL-T06	OKL-T07	OKL-T08	OKL-T09
	OKL-T10	OKL-T11	OKL-T12						
OKL-Y	OKL-Y01	OKL-Y02	OKL-Y03	OKL-Y04	OKL-Y05	OKL-Y06	OKL-Y07	OKL-Y08	
OKL-X	OKL-X01	OKL-X02	OKL-X03	OKL-X04	OKL-X05	OKL-X06			
OKL-A	OKL-A01	OKL-A02	OKL-A03	OKL-A04	OKL-A05	OKL-A06	OKL-A07	OKL-A08	OKL-A09
	OKL-A10	OKL-A11	OKL-A12	OKL-A13	OKL-A14				
OKL-L	OKL-L01	OKL-L02	OKL-L03	OKL-L04	OKL-L05	OKL-L06	OKL-L07		
OKL-Z	OKL-Z01	OKL-Z02	OKL-Z03	OKL-Z04	OKL-Z05				
OKL-J	OKL-J01	OKL-J02	OKL-J03	OKL-J04					
OKL-D	OKL-D01	OKL-D02	OKL-D03	OKL-D04	OKL-D05	OKL-D06	OKL-D07	OKL-D08	
OKL-F	OKL-F01	OKL-F02	OKL-F03	OKL-F04	OKL-F05	OKL-F06	OKL-F07	OKL-F08	
OKL-B	OKL-B01	OKL-B02	OKL-B03	OKL-B04	OKL-B05	OKL-B06	OKL-B07	OKL-B08	OKL-B09
	OKL-B10	OKL-B11	OKL-B12	OKL-B13	OKL-B14	OKL-B15	OKL-B16	OKL-B17	OKL-B18
	OKL-B19	OKL-B20	OKL-B21	OKL-B22					
OKL-M	OKL-M01	OKL-M02	OKL-M03	OKL-M04	OKL-M05	OKL-M06	OKL-M07	OKL-M08	OKL-M09
	OKL-M10								
OKL-S	OKL-S01	OKL-S02	OKL-S03						
OKL-SD	OKL-SD01	OKL-SD02	OKL-SD03	OKL-SD04	OKL-SD05	OKL-SD06	OKL-SD07		
OKL-K	OKL-K01	OKL-K02	OKL-K03	OKL-K04	OKL-K05	OKL-K06			
OKL-C	OKL-C01	OKL-C02	OKL-C03	OKL-C04	OKL-C05	OKL-C06	OKL-C07	OKL-C08	OKL-C09
	OKL-C10	OKL-C11	OKL-C12	OKL-C13	OKL-C14	OKL-C15	OKL-C16	OKL-C17	OKL-C18
	OKL-C19	OKL-C20							