



DEVICE DETAILS

NAME OF DEVICE	PULSE OXIMETER OLV-4201
ESTABLISHMENT NAME	NIHON KOHDEN MALAYSIA SDN BHD
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GC95939699418
BRAND NAME	NIHON KOHDEN (OLV-4201)
MEDICAL DEVICE CATEGORY	MD 1302 - Monitoring devices of vital physiological parameters
DEVICE GROUPING TYPE	SYSTEM
DEVICE DESCRIPTION	THE PULSE OXIMETER IS A COMPACT MONITOR WITH A 7-INCH DISPLAY AND IS DESIGNED FOR TOUCHSCREEN OPERATION AT THE PATIENT'S SIDE. THE PULSE OXIMETER IS INSTALLED NEAR THE PATIENT TO DISPLAY THE PATIENT'S VITAL SIGNS (SPO2, PULSE RATE, ETC.) ON THE DISPLAY AND GENERATE ALARMS. NEONATES, CHILDREN AND ADULTS CAN BE MONITORED WITH THIS PULSE OXIMETER. WHEN THE OPERATION MODE IS SET TO NETWORK MODE, THE PULSE OXIMETER CAN CONNECT TO A NIHON KOHDEN CENTRAL MONITOR NETWORK AND COMMUNICATE WITH CENTRAL MONITORS AND BEDSIDE MONITORS IN THE NETWORK.
DEVICE INTENDED PURPOSE	THE PULSE OXIMETER IS INSTALLED NEAR THE PATIENT TO DISPLAY THE PATIENT'S VITAL SIGNS (SPO2, PULSE RATE, ETC.) ON THE DISPLAY AND GENERATE ALARMS. THIS PULSE OXIMETER MUST BE USED BY QUALIFIED MEDICAL PERSONNEL WITH FULL KNOWLEDGE OF ITS FUNCTIONS AND OPERATIONS WITHIN THE ENVIRONMENT OF HOSPITALS SUCH AS CRITICAL CARE, ICU, HCU, OR, GCU, OUTPATIENT CLINIC, GENERAL WARD AND SO ON. IT IS NOT INTENDED FOR PATIENTS TO USE. IT IS NOT INTENDED TO USE OUTSIDE OR AT HOME, EITHER.
VALIDITY DATE OF REGISTRATION	22/02/2018 - 21/02/2023

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	Pulse Oximeter, OLV-4201	OLV-4201
2	Power cord N	Power cord N
3	Power cord UL	Power cord UL
4	Battery pack, SB-170P	SB-170P
5	Transmitter, ZS-900PG	ZS-900PG

NO	NAME OF DEVICE	IDENTIFIER
6	Transmitter, ZS-900PK	ZS-900PK
7	Software kit, QS-007TA	QS-007TA
8	Software kit, QS-007TK	QS-007TK
9	SpO2 connection cable, JL-400T	JL-400T
10	SpO2 connection cable, JL-430U	JL-430U
11	SpO2 connection cable, JL-030U1	JL-030U1
12	SpO2 connection cable, JL-030U2	JL-030U2
13	HFAS switch, RY-420T	RY-420T
14	Site label, YS-113P0	YS-113P0
15	Ground lead, L913	L913
16	Cart, KC-170P	KC-170P
17	Adapter, DH-171P	DH-171P
18	Adapter, DH-172P	DH-172P
19	ZS holder, DH-380P	DH-380P
20	Finger probe, TL-201T	TL-201T
21	Finger probe, TL-630T3	TL-630T3
22	Finger probe, TL-600T0	TL-600T0
23	Finger probe, TL-630T1	TL-630T1
24	Finger probe, TL-631T1	TL-631T1
25	Finger probe, TL-631T3	TL-631T3
26	Finger probe, TL-601T0	TL-601T0
27	Multi-site probe, TL-220T	TL-220T
28	Disposable SpO2 probe, TL-271T	TL-271T
29	Disposable SpO2 probe, TL-271T3	TL-271T3
30	Disposable SpO2 probe, TL-272T	TL-272T
31	Disposable SpO2 probe, TL-272T3	TL-272T3



MEDICAL DEVICE AUTHORITY

NO	NAME OF DEVICE	IDENTIFIER
32	Disposable SpO2 probe, TL-273T	TL-273T
33	Disposable SpO2 probe, TL-273T3	TL-273T3
34	Disposable SpO2 probe, TL-274T	TL-274T
35	Disposable SpO2 probe, TL-274T3	TL-274T3
36	Disposable Multi-site Y probe, TL-260T	TL-260T
37	Disposable SpO2 probe, TL-051S	TL-051S
38	Disposable SpO2 probe, TL-052S	TL-052S
39	Disposable SpO2 probe, TL-061S	TL-061S
40	Disposable SpO2 probe, TL-062S	TL-062S
41	Disposable SpO2 probe, TL-535U	TL-535U
42	Attachment tape, P263	P263
43	Sponge attachment tape, P260A	P260A
44	Sponge attachment tape, P260B	P260B
45	Clip adapter, P256	P256
46	Fixing tape for disposable probes, P260C	P260C
47	Attachment tape, P264A	P264A
48	Attachment tape, P264B	P264B
49	Probe fastener, YS-093P2	YS-093P2