



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	22/02/2023 - 21/02/2028

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-007TK	QS-007TK
8	SpO2 connection cable, JL-400T	JL-400T
9	SpO2 connection cable, JL-430U	JL-430U
10	SpO2 connection cable, JL-030U1	JL-030U1
11	SpO2 connection cable, JL-030U2	JL-030U2
12	Ground lead, L913	L913
13	Cart, KC-170P	KC-170P
14	Adapter, DH-171P	DH-171P
15	Adapter, DH-172P	DH-172P
16	ZS holder, DH-380P	DH-380P
17	Finger probe, TL-201T	TL-201T
18	Finger probe, TL-630T3	TL-630T3
19	Finger probe, TL-630T1	TL-630T1
20	Finger probe, TL-631T1	TL-631T1
21	Finger probe, TL-631T3	TL-631T3
22	Finger probe, TL-601T0	TL-601T0
23	Multi-site probe, TL-220T	TL-220T
24	Disposable SpO2 probe, TL-271T	TL-271T
25	Disposable SpO2 probe, TL-271T3	TL-271T3
26	Disposable SpO2 probe, TL-272T	TL-272T
27	Disposable SpO2 probe, TL-272T3	TL-272T3
28	Disposable SpO2 probe, TL-273T	TL-273T
29	Disposable SpO2 probe, TL-273T3	TL-273T3
30	Disposable SpO2 probe, TL-274T	TL-274T
31	Disposable SpO2 probe, TL-274T3	TL-274T3

NO	NAME OF DEVICE	IDENTIFIER
32	Disposable Multi-site Y probe, TL-260T	TL-260T
33	Disposable SpO2 probe, TL-535U	TL-535U
34	Clip adapter, P256	P256
35	Fixing tape for disposable probes, P260C	P260C
36	Attachment tape, P264A	P264A
37	Attachment tape, P264B	P264B
38	Probe fastener, YS-093P2	YS-093P2



MEDICAL DEVICE AUTHORITY