

DEVICE DETAILS

NAME OF DEVICE	G3 PULSE OXIMETER
ESTABLISHMENT NAME	PHILIPS MALAYSIA SDN BERHAD
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GC58276545418
BRAND NAME	PHILIPS GOLDWAY
MEDICAL DEVICE CATEGORY	MD 1302 - Monitoring devices of vital physiological parameters
DEVICE GROUPING TYPE	SYSTEM
DEVICE DESCRIPTION	THE GOLDWAY G3 IS A COST EFFECTIVE, AND EASY TO USE. DESIGNED FOR MONITORING IMPORTANT OXYGEN SATURATION MEASUREMENTS IN ADULT, PEDIATRIC AND NEONATAL PATIENTS, IT OFFERS SPO2 AND PR MEASUREMENT PARAMETER, AS WELL AS 500 SET OF TREND DATA IN A COMPACT ,EASY TO CARRY DESIGN. G3 PULSE OXIMETER IS CONSISTED OF MAIN CONTROLLING BOARD, MEASURING FUNCTIONAL MODULE AND DISPLAY MODULE. CONNECTING TO HUMAN BODY WITH SPO2 SENSOR, IT MEASURES THE PHYSIOLOGICAL SIGNAL SUCH AS SPO2 AND PR AND CONVERTS THEM INTO DATA WHICH CAN BE DISPLAYED, ANALYZED AND SAVED TO PUT FORWARD MONITORING ON THE PATIENTS.
DEVICE INTENDED PURPOSE	THE G3 PULSE OXIMETER IS INTENDED FOR MONITORING AND ALARMING OF PHYSIOLOGICAL PARAMETERS OF ADULTS, PEDIATRICS AND NEONATES IN HEALTHCARE ENVIRONMENTS. THE G3 PULSE OXIMETER IS FOR HEALTHCARE PROFESSIONALS WHENEVER THERE IS A NEED FOR MONITORING PHYSIOLOGICAL PARAMETERS OF PATIENTS.
VALIDITY DATE OF REGISTRATION	28/12/2017 - 27/12/2022

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	Pulse Oximeter	G3
2	Adult/ Pediatric Clip sensor for patient size > 88 lb (40 kg)	M1196A
3	Adult Clip sensor for patient size > 110 lb (50 kg)	M1196S
4	Pediatric/ Small Adult Finger sensor for patient size 33 - 110 lb (15 - 50 kg)	M1192A
5	Adult Finger sensor for patient size > 110 lb (50kg)	M1191B
6	Adult Finger sensor forpatient size > 110 lb (50kg)	M1191BL
7	Neonatal Foot/hand sensor for patient size 2.2 - 8.8 lb (1 - 4 kg)	M1193A

NO	NAME OF DEVICE	IDENTIFIER
8	Infant Foot sensor for patient size 8.8 - 33 lb (4 - 15 kg)	M1195A
9	Adult Ear clip for patient size > 88 lb (40kg)	M1194A
10	Adult/ Pediatric Finger sensor for patient size > 110 lb (50kg)	M1131A
11	Infant Digit sensor for patient size 7 - 22 lb (3 - 10 kg)	M1132A
12	Neonatal/ Infant/Adult Foot/hand sensor for neonatal; big toe/ thumb for infant; finger for adult. Neonatal patient size: < 7 lb (3kg); infant patient size: 22 - 44 lb (10 - 20 kg); adult patient size: >88 lb (40kg)	M1133A
13	adapter cable	M1943A
14	adapter cable	M1943AL
15	Neonatal/ Adult Sensor for neonatal, foot, or adult digit for patient size <7 lb or > 88 lb (<3 kg or >40 kg). Identical to OxiMax MAX-N	M1901B
16	Infant Digit sensor, for patient size 7 - 44 lb (3-20 kg). Identical to OxiMax MAX-I	M1902B
17	Pediatric Digit sensor, for patient size 22-110 lb (10 - 50 kg). Identical to OxiMax MAX-P	M1903B
18	Adult Digit sensor, for patient size >66 lb (>30 kg). Identical to OxiMax MAX-A	M1904B
19	Masimo LNOP Adapter Cable (adapts LNOP sensors to Philips monitors)	M1020-61100
20	Masimo LNCS Adapter Cable (adapts LNCS sensors to Philips monitors)	989803148221