



DEVICE DETAILS

NAME OF DEVICE	INVOS 5100C CEREBRAL/SOMATIC OXIMETER & ACCESSORIES
ESTABLISHMENT NAME	MEDTRONIC MALAYSIA SDN BHD
REGISTRATION NO	GC39155628318
BRAND NAME	INVOS
DEVICE GROUPING TYPE	SYSTEM
DEVICE DESCRIPTION	THE INVOS CEREBRAL/SOMATIC OXIMETER MODEL 5100C IS A PATIENT MONITOR THAT CONTINUOUSLY AND NONINVASIVELY MEASURES THE BLOOD OXYGEN SATURATION IN CEREBRAL OR SOMATIC REGION OF THE BODY, FOR ADULT OR PEDIATRIC APPLICATION.
DEVICE INTENDED PURPOSE	THE NONINVASIVE INVOS 5100C IS INTENDED FOR USE AS AN ADJUNCT MONITOR OF REGIONAL HEMOGLOBIN OXYGEN SATURATION OF BLOOD IN THE BRAIN OR IN OTHER TISSUE BENEATH THE SENSOR. IT IS INTENDED FOR USE IN INDIVIDUALS GREATER THAN 2.5 KG AT RISK FOR REDUCED-FLOW OR NO-FLOW ISCHEMIC STATES. IT IS ALSO INTENDED FOR USE AS AN ADJUNCT TREND MONITOR OF REGIONAL HEMOGLOBIN OXYGEN SATURATION OF BLOOD IN THE BRAIN OR IN OTHER TISSUE BENEATH THE SENSOR IN ANY INDIVIDUAL.
VALIDITY DATE OF REGISTRATION	11/01/2018 - 10/01/2023

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	INVOS Regional Saturation Patient Monitor	5100C-EU
2	INVOS Regional Saturation Patient Interface Module	5100C-PA
3	INVOS Regional Saturation Patient Interface Module	5100C-PB
4	INVOS Regional Saturation Patient Interface Module	5100C-PA-INT
5	INVOS Regional Saturation Patient Interface Module	5100C-PB-INT
6	INVOS Regional Saturation Patient Interface Cable	RSC-1
7	INVOS Regional Saturation Patient Interface Cable	RSC-2
8	INVOS Regional Saturation Patient Interface Cable	RSC-3
9	INVOS Regional Saturation Patient Interface Cable	RSC-4
10	INVOS Adult Regional Saturation Sensor	SAFB

NO	NAME OF DEVICE	IDENTIFIER
11	INVOS Pediatric Regional Saturation Sensor	SPFB
12	INVOS Pediatric Regional Saturation Sensor	SPFBX10
13	INVOS Pediatric Regional Saturation Sensor	SPFBX20
14	INVOS Adult Regional Saturation Sensor	SAFB-SM
15	INVOS Adult Regional Saturation Sensor	SAFB-SMX10
16	INVOS Adult Regional Saturation Sensor	SAFB-SMX20
17	INVOS Adult Regional Saturation Sensor	SAFB-SM/INTL
18	INVOS Adult Regional Saturation Sensor	SAFB-SM/INTL20
19	INVOS Pediatric Regional Saturation Sensor	SPFB/INTL
20	INVOS Pediatric Regional Saturation Sensor	SPFB/INTL20
21	INVOS Infant Regional Saturation Sensor Cerebral	CNN
22	INVOS Infant Regional Saturation Sensor Somatic	SNN
23	INVOS Infant Regional Saturation Sensor Cerebral/Somatic	CNN/SNN
24	5100C MULTILINGUAL CD SW 40.10.10	314039
25	INVOS Adapter Plate	5100C-GCX
26	INVOS Roll Stand	5100C-RS
27	INVOS Swivel Arm	5100C-SA
28	INVOS USB Flash Drive	5100C-USB