



DEVICE DETAILS

NAME OF DEVICE	PULSE OXIMETER (H100N, H100B)
ESTABLISHMENT NAME	KORMED RESOURCES PLT.
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GC374031090618
BRAND NAME	EDAN
MEDICAL DEVICE CATEGORY	MD 1300 - MONITORING DEVICES
DEVICE GROUPING TYPE	FAMILY
DEVICE DESCRIPTION	H100B AND H100N (BOTH IN FIGURE 1) ARE MODELS OF H100 SERIES PULSE OXIMETER. IT DISPLAYS SPO2 VALUE, PULSE RATE VALUE, PLETHYSMOGRAM, BAR GRAPH, TEMPERATURE, ETC. H100B IS INSTALLED WITH EDAN SPO2 MODULE INSIDE. H100N IS INSTALLED WITH NELLCOR SPO2 MODULE AND THE MANUFACTURER'S TEMP MODULE INSIDE. IT INTEGRATES PARAMETER MODULE, DISPLAY AND DATA OUTPUT FUNCTIONS.
DEVICE INTENDED PURPOSE	THE H100B PULSE OXIMETER IS INTENDED FOR CONTINUOUS MONITORING OR SPOT-CHECKING OF FUNCTIONAL ARTERIAL OXYGEN SATURATION (SPO2) AND PULSE RATE OF SINGLE ADULT, PEDIATRIC OR NEONATE PATIENT IN HOSPITALS, INTRA-HOSPITAL TRANSPORT AND HOSPITAL TYPE FACILITIES.
VALIDITY DATE OF REGISTRATION	26/09/2018 - 25/09/2023

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	Pulse Oximeter	H100B
2	Pulse Oximeter	H100N