



DEVICE DETAILS

NAME OF DEVICE	PULSE OXIMETER
ESTABLISHMENT NAME	KORMED RESOURCES PLT.
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GC3134223-121051
BRAND NAME	EDAN
MEDICAL DEVICE CATEGORY	MD 1302 - Monitoring devices of vital physiological parameters
DEVICE GROUPING TYPE	FAMILY
DEVICE DESCRIPTION	<p>H100B&H100N are models of H100 series Pulse Oximeter. They display SpO₂ value, pulse rate value, plethysmogram, bar graph, temperature (only for H100N), etc. H100B is installed with EDAN SpO₂ module inside. H100N is installed with Nellcor SpO₂ module and the manufacturer's TEMP module inside. They both integrate parameter module, display and data output functions. They can be powered by four 1.5 V AA batteries or four 1.2 V Rechargeable Ni-MH AA batteries. They can clearly display all the parameter information on LCD. 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. H100N Pulse Oximeter (hereinafter called oximeter) is one model of H100 series Pulse Oximeter. The oximeter is intended for continuous monitoring or spot-checking of functional arterial oxygen saturation (SpO₂), pulse rate and for oral, axillary and rectal temperature measurement. It is intended to be used on adult, pediatric or neonatal patient in hospitals, intra-hospital transport and hospital type facilities. The software version of H100B is V2.6, the software version of H100N is V1.6, and they were developed to V2.6 and V1.6 separately to add display electric quantity of battery.</p>
DEVICE INTENDED PURPOSE	<p>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. H100N Pulse Oximeter (hereinafter called oximeter) is one model of H100 series Pulse Oximeter. The oximeter is intended for continuous monitoring or spot-checking of functional arterial oxygen saturation (SpO₂), pulse rate and for oral, axillary and rectal temperature measurement. It is intended to be used on adult, pediatric or neonatal patient in hospitals, intra-hospital transport and hospital type facilities.</p>
VALIDITY DATE OF REGISTRATION	24/02/2023 - 23/02/2028

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
No results found.		



MEDICAL DEVICE AUTHORITY