

DEVICE DETAILS		
NAME OF DEVICE	PULSE OXIMETER	
ESTABLISHMENT NAME	KORMED RESOURCES PLT.	
REGISTRATION NO	GC3134223-121051	
BRAND NAME	EDAN	
DEVICE GROUPING TYPE	FAMILY	
DEVICE DESCRIPTION	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.	
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. 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.	
VALIDITY DATE OF REGISTRATION	24/02/2023 - 23/02/2028	

LIST OF DEVICE			
NO	NAME OF DEVICE	IDENTIFIER	
No results found.			