



## DEVICE DETAILS

NAME OF DEVICE	MULTI-4 CO-OXIMETER CONTROLS
ESTABLISHMENT NAME	STRAITS SCIENTIFIC (M) SDN BHD
REGISTRATION NO	IVDB8543919-35138
BRAND NAME	MULTI-4
DEVICE GROUPING TYPE	IVD CLUSTER
DEVICE DESCRIPTION	Multi-4 CO-Oximeter Control is comprised of the following ampule configurations: Level 1: with high THb, low %O2Hb and high %COHb consistent with values observed with victims of smoke inhalation and other similar situations. Level 2: is consistent with values observed in the normal population. Level 3: with low THb consistent with anemic patients. The %O2Hb and %COHB reflect low clinical threshold levels.
DEVICE INTENDED PURPOSE	Multi-4 CO-Oximeter™ Control is a quality control material available in three levels designed to simulate conditions of tissue oxygenation.
VALIDITY DATE OF REGISTRATION	01/10/2019 - 30/09/2024

## LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	Multi-4 CO-Oximeter Control L1	0003315250
2	Multi-4 CO-Oximeter Control L2	0003314250
3	Multi-4 CO-Oximeter Control L3	0003313250
4	Multi-4 CO-Oximeter Control Multi Pack	0003316200