



DEVICE DETAILS

NAME OF DEVICE	AUTOMATED CLINICAL CHEMISTRY ANALYZER
ESTABLISHMENT NAME	FUJIFILM (MALAYSIA) SDN. BHD.
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	IVDA5572198918
BRAND NAME	FUJIFILM
MEDICAL DEVICE CATEGORY	SUBSTRATE ELECTRODES/BIOSENSORS
DEVICE GROUPING TYPE	FAMILY
DEVICE DESCRIPTION	FUJI DRI-CHEM AUTOMATED CLINICAL CHEMISTRY ANALYZER PERFORMS A VERY SIMPLE BIOCHEMICAL TEST SYSTEM THAT CAN MEASURE THE CONCENTRATION OR ACTIVITY OF SPECIFIC SUBSTANCE OR ENZYMES BY A DROP OF BLOOD PLASMA/SERUM OR URINE ON A SMALL SLIDE CONTAINING DRY REAGENTS.
DEVICE INTENDED PURPOSE	FOR IN VITRO DIAGNOSTIC USE. THE DEVICE IS USED TO QUANTITATES THE CONCENTRATION OR THE ACTIVITY OF THE COMPONENTS IN BLOOD/URINE BY USING THE FUJI DRI-CHEM SLIDES (DRIED REAGENTS).
VALIDITY DATE OF REGISTRATION	28/12/2017 - 27/12/2022

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	FUJI DRI-CHEM NX500	FDC NX500 E MJ
2	FUJI DRI-CHEM NX500i	FDC NX500 I E J
3	FUJI DRI-CHEM 7000i	FDC 7000 I E 2
4	FUJI DRI-CHEM 4000ie	FDC 4000 I E
5	FUJI DRI-CHEM NX700	FDC NX700 E
6	FUJI DRI-CHEM NX700i	FDC NX700 I E
7	FUJI DRI-CHEM NX600	FDC NX600 E
8	FUJI DRI-CHEM NX600i	FDC NX600 I E