



## DEVICE DETAILS

<b>NAME OF DEVICE</b>	AUTOMATED CLINICAL CHEMISTRY ANALYZER
<b>ESTABLISHMENT NAME</b>	FUJIFILM (MALAYSIA) SDN. BHD.
<b>ROLE OF ESTABLISHMENT</b>	AUTHORIZED REPRESENTATIVE
<b>REGISTRATION NO</b>	IVDA5572198918
<b>BRAND NAME</b>	FUJIFILM
<b>MEDICAL DEVICE CATEGORY</b>	SUBSTRATE ELECTRODES/BIOSENSORS
<b>DEVICE GROUPING TYPE</b>	FAMILY
<b>DEVICE DESCRIPTION</b>	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.
<b>DEVICE INTENDED PURPOSE</b>	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).
<b>VALIDITY DATE OF REGISTRATION</b>	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