

DEVICE DETAILS

NAME OF DEVICE	ONE TOUCH SELECTSIMPLE BLOOD GLUCOSE MONITORING SYSTEM
ESTABLISHMENT NAME	DKSH MALAYSIA SDN BHD
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	IVDC7890023417
BRAND NAME	ONE TOUCH
MEDICAL DEVICE CATEGORY	SELF TESTING
DEVICE GROUPING TYPE	SYSTEM
DEVICE DESCRIPTION	THE ONETOUCH SELECTSIMPLE [®] ; BLOOD GLUCOSE MONITORING SYSTEM CONSISTS OF: - ONETOUCH SELECTSIMPLE [®] ; METER - ONETOUCH SELECT [®] ; TEST STRIPS - ONETOUCH SELECT [®] ; CONTROL SOLUTION - ONETOUCH [®] ; LANCING DEVICE - ONETOUCH ULTRASOFT [®] ; LANCET
DEVICE INTENDED PURPOSE	THE ONETOUCH SELECTSIMPLE [®] ; BLOOD GLUCOSE MONITORING SYSTEM IS INTENDED TO BE USED FOR QUANTITATIVE MEASUREMENT OF GLUCOSE IN FRESH CAPILLARY WHOLE BLOOD. THE ONETOUCH SELECTSIMPLE [®] ; SYSTEM IS INTENDED FOR USE OUTSIDE THE BODY (IN VITRO DIAGNOSTIC USE) BY PEOPLE WITH DIABETES AT HOME AND/OR BY HEALTHCARE PROFESSIONALS IN A CLINICAL SETTING AS AN AID TO MONITOR THE EFFECTIVENESS OF DIABETES CONTROL. IT SHOULD NOT BE USED FOR THE DIAGNOSIS OF DIABETES OR TESTING OF NEWBORNS. THE ONETOUCH SELECTSIMPLE [®] ; BLOOD GLUCOSE MONITORING SYSTEM IS SPECIFICALLY INDICATED FOR USE ON THE FINGER, FOREARM OR PALM.
VALIDITY DATE OF REGISTRATION	26/04/2022 - 25/04/2027

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	OneTouch [®] ; UltraSoft [®] ; Lanset	020-797
2	OneTouch [®] ; Select [®] ; Control Solution	022-349
3	OneTouch [®] ; Select [®] ; Test Strips	022-347
4	OneTouch [®] ; Select [®] ; Test Strips	022-346
5	OneTouch [®] ; SelectSimple [®] ; Blood Glucose Meter	022-367

NO	NAME OF DEVICE	IDENTIFIER
6	OneTouch®; SelectSimple®; Blood Glucose Monitoring System	022-345
7	OneTouch®; UltraSoft®; Lanset	020-798



MEDICAL DEVICE AUTHORITY