



DEVICE DETAILS

NAME OF DEVICE	WRIST BLOOD PRESSURE MONITOR
ESTABLISHMENT NAME	HUAWEI TECHNOLOGIES (MALAYSIA) SDN BHD
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GB2822524-166644
BRAND NAME	HUAWEI
MEDICAL DEVICE CATEGORY	MD 0100 - GENERAL NON-ACTIVE, NON-IMPLANTABLE MEDICAL DEVICES
DEVICE GROUPING TYPE	FAMILY
DEVICE DESCRIPTION	The Wrist Blood Pressure Monitor manufactured by Huawei Device Co., Ltd. (hereafter referred to as Huawei) is a reusable, active, non-sterile, non-invasive and non-implantable device for measuring adults' blood pressure and pulse rate. It is a home-use device prohibited from use in MRI (magnetic resonance imaging) environment.
DEVICE INTENDED PURPOSE	The Wrist Blood Pressure Monitor is a digital self-monitor intended for use in measuring blood pressure and pulse rate in adult patient population with wrist circumference ranging from 13.0 cm to 20.0 cm (5.12–7.87 inches).
VALIDITY DATE OF REGISTRATION	19/03/2024 - 18/03/2029

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	Wrist Blood Pressure Monitor	MLY-B10
2	Wrist Blood Pressure Monitor	MLY-B11
3	Wrist Ambulatory Blood Pressure Monitor	LCA-B10
4	Wrist Ambulatory Blood Pressure Monitor	LCA-B11