



DEVICE DETAILS

NAME OF DEVICE	3 Ply Surgical Face Mask - Tie On
ESTABLISHMENT NAME	ASPEN ANGKASA SDN BHD
ROLE OF ESTABLISHMENT	MANUFACTURER
REGISTRATION NO	GA5748522-96062
BRAND NAME	McDICA
MEDICAL DEVICE CATEGORY	SINGLE-USE DEVICES
DEVICE GROUPING TYPE	FAMILY
DEVICE DESCRIPTION	The mask provides a physical barrier to block pollutants from nose and mouth and to reduce risks of spreading viruses and breathing in airborne particles. • Face Seal Fit (Loose-Fitting). • No Fit-Testing Requirement. • Does not provide the wearer with a reliable level of protection from inhaling smaller airborne particles and is NOT considered respiratory protection.
DEVICE INTENDED PURPOSE	The mask with hygiene barrier property is intended to be worn by doctor, nurse, and patient to cover the user's nose and mouth.
VALIDITY DATE OF REGISTRATION	27/06/2022 - 26/06/2027

LIST OF DEVICE

NO	NAME OF DEVICE 	IDENTIFIER
1	3PLY SURGICAL FACE MASK TIE-ON	McDICA
2	3PLY SURGICAL FACE MASK TIE-ON	McDICA
3	3PLY SURGICAL FACE MASK TIE-ON	McDICA