



DEVICE DETAILS

NAME OF DEVICE	Monoart Face Mask
ESTABLISHMENT NAME	AR DENTAL SUPPLIES SDN BHD
REGISTRATION NO	GA9608019-35032
BRAND NAME	Euronda
DEVICE GROUPING TYPE	FAMILY
DEVICE DESCRIPTION	The Monoart® Face Masks are disposable medical devices and have been developed to offer total operational protection (the same standards as the Protection 4 range), but they also deliver the safety levels of hypo-allergenic materials which have been carefully sourced to respect sensitive skins and avoid the risk of irritation and dermatitis.
DEVICE INTENDED PURPOSE	Disposable hypo-allergenic face mask, composed by 4 layers: • Soft, coloured and water-repellent non-woven fabric with floral motifs; • PFE (Particle Filtration Efficiency) filter and BFE (Bacterial Filtration Efficiency) > 99%; • 2 layers of comfortable, absorbent non-woven fabric lining for effective absorption of sweat and moisture. It is ideal for protection from dust and aerosols: $\Delta P < 3.0 \text{ mm H}_2\text{O}/\text{cm}^2$ in accordance with the EN 14683 standard (differential pressure: surgical mask breathability rating). Built-in nose bridge.
VALIDITY DATE OF REGISTRATION	03/10/2019 - 02/10/2024

LIST OF DEVICE

MEDICAL DEVICE AUTHORITY

NO	NAME OF DEVICE	IDENTIFIER
1	MONOART®FACE MASKPRO.3L.BLUEBOX/50	217112
2	MONOART®FACE MASKPRO.3GREENBOX/50	217114
3	MONOART®FACE MASKPRO.3WHITEBOX/50	217118
4	MONOART®FACE MASKPRO.3YELLOWBOX/50	217116
5	MONOART®FACE MASKPRO.3ORANGEBOX/50	217115
6	MONOART®FACE MASKPRO.3PINKBOX/50	217117
7	MONOART®FACE MASKPRO.3LILABOX/50	217119
8	MONOART®FACE MASKPRO.3LIMEBOX/50	217120
9	MONOART®FACE MASKPRO.3B.LAGOONBOX/50	217127
10	MONOART®FACEMASK PRO.3 FLORAL PINK	217121

NO	NAME OF DEVICE	IDENTIFIER
11	MONOART®FACEMASK PRO.3 FLORAL LILAC	217122
12	MONOART®FACEMASK PRO.3 FLORAL LIME	217123
13	MONOART®FACEMASK PRO.3 FLORAL LIGHT BLUE	217124
14	MONOART®FACEMASK PRO.3 FLORAL BURGUNDY	217126
15	MONOART®FACEMASKPRO.4L.BLUEBOX/50	217132
16	MONOART®FACEMASKPRO.4GREENBOX/50	217134
17	MONOART®FACEMASKPRO.4ORANGEBOX/50	217135
18	MONOART®FACEMASKPRO.4BLACKBOX/50	217143
19	MONOART®FACEMASKPRO.4L.SENSITIVEBOX/50	217141

