




## DEVICE DETAILS

NAME OF DEVICE	Fluidshield Face Mask
ESTABLISHMENT NAME	HALYARD MALAYSIA SDN BHD
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GA10546319-32171
BRAND NAME	HALYARD*
MEDICAL DEVICE CATEGORY	SINGLE-USE DEVICES
DEVICE GROUPING TYPE	FAMILY
DEVICE DESCRIPTION	FLUIDSHIELD Masks incorporate four layers of barrier protection including a layer of LONCET breathable film which protects the health care worker from blood and body fluids while maintaining a high degree of breathability.
DEVICE INTENDED PURPOSE	Surgical masks are devices that are intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material.
VALIDITY DATE OF REGISTRATION	05/08/2024 - 04/08/2029

## LIST OF DEVICE

NO	NAME OF DEVICE 	IDENTIFIER
1	FLUIDSHIELD* 3 Fog-Free Surgical Mask with So Soft* Lining	48207
2	FLUIDSHIELD* 3 Surgical Mask with So Soft* Lining	48208
3	FLUIDSHIELD* 3 Fog-Free Surgical Mask with So Soft* Lining, Orange, Visor	48237
4	FLUIDSHIELD* 3 Fog-Free Surgical Mask with SO SOFT* Lining, Orange, Anti-Glare WrapAround Visor	48247
5	FLUIDSHIELD* 3 Teddy Bear Surgical Mask with SO SOFT* Lining	48297
6	FLUIDSHIELD* 2 Fog-Free Surgical Mask	62113
7	FLUIDSHIELD* 2 Fog-Free Surgical Mask, Blue with Orange Print, WrapAround Visor	62114
8	FLUIDSHIELD* 3 Fog-Free Procedure Mask with SO SOFT* Lining and SO SOFT* Earloops	47147
9	FLUIDSHIELD* 3 Fog-Free Procedure Mask with SO SOFT* Lining and SO SOFT* Earloops	47137
10	FLUIDSHIELD* 3 Fog-Free Procedure Mask with SO SOFT* Lining and SO SOFT* Earloops	47107

NO	NAME OF DEVICE	IDENTIFIER
11	FLUIDSHIELD* 3 Fog-Free Procedure Mask with SO SOFT* Earloops	28797

