



DEVICE DETAILS

NAME OF DEVICE	N95 Face Mask
ESTABLISHMENT NAME	HALYARD MALAYSIA SDN BHD
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GA9457719-32152
BRAND NAME	HALYARD*
MEDICAL DEVICE CATEGORY	SINGLE-USE DEVICES
DEVICE GROUPING TYPE	FAMILY
DEVICE DESCRIPTION	N95 Face Masks are NIOSH approved and offers a high level of respiratory protection with an effective facial fit. These masks provide optimal fluid protection and come in a choice of styles and sizes.
DEVICE INTENDED PURPOSE	N95 Face 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 N95 Particulate Filter Respirator and Surgical Mask with SO SOFT* Lining, Orange, Regular Size	46727
2	FLUIDSHIELD* 3 N95 Particulate Filter Respirator and Surgical Mask with SO SOFT* Lining, Orange, Regular Size, Individually Packaged	46728
3	FLUIDSHIELD* 3 N95 Particulate Filter Respirator and Surgical Mask with Safety Seal and SO SOFT* Lining, Orange, Regular Size	46767
4	FLUIDSHIELD* 3 N95 Particulate Filter Respirator and Surgical Mask with SO SOFT* Lining, Orange, Small	46827
5	FLUIDSHIELD* 3 N95 Particulate Filter Respirator and Surgical Mask with SO SOFT* Lining, Orange, Small Size, Individually Packaged	46828
6	FLUIDSHIELD* 3 N95 Particulate Filter Respirator and Surgical Mask with Safety Seal and SO SOFT* Lining, Orange, Small	46867
7	FLUIDSHIELD* 2 N95 Particulate Filter Respirator and Surgical Mask with SO SOFT* Lining, White, Regular Size	62126
8	FLUIDSHIELD* 2 N95 Particulate Filter Respirator and Surgical Mask with SO SOFT* Lining, White, Small	62355

NO	NAME OF DEVICE	IDENTIFIER
9	FLUIDSHIELD* 3 Ported N95 Particulate Filter Respirator with SAFETY SEAL and SO SOFT* Lining, Orange, Regular Size	99178
10	FLUIDSHIELD* 3 Ported N95 Particulate Filter Respirator with SO SOFT* Lining, Orange, Small Size	99181
11	FLUIDSHIELD* 3 Ported N95 Particulate Filter Respirator with SAFETY SEAL and SO SOFT* Lining, Orange, Small Size	99184

