



DEVICE DETAILS

NAME OF DEVICE	DRAEGER LITESTAR DISPOSABLE FACE MASK
ESTABLISHMENT NAME	DRAEGER MALAYSIA SDN BHD
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GB1423822-82734
BRAND NAME	DRAEGER
MEDICAL DEVICE CATEGORY	MD 0101 - Non-active devices for anaesthesia, emergency and intensive care
DEVICE GROUPING TYPE	FAMILY
DEVICE DESCRIPTION	<p>Anesthesia masks are accessories of anesthesia devices. They support the application of medical gases in the patient's upper airway without the need to insert any additional devices in the trachea. Anesthesia masks are in direct contact with the patient face and breathing gas. The application of the anaesthesia masks occurs under direct human supervision. LiteStar anaesthesia face mask is disposable as well. The teardrop shape of the mask supports an anatomical fit. The transparent mask body allows for continuous observation of the patient's conditions. The reinforcing ring placed around the mask connector provides stable connection with breathing circuit systems. There is a new generation of LiteStar masks. The new portfolio was extended to another size (size 7) and the design was optimized. An easy application is supported by additional mask accessories: hook rings and headgears for fixation. Two different headgears in small and large designs offer patients and physicians a soft and elastic fixation.</p>
DEVICE INTENDED PURPOSE	Disposable anesthesia mask for the application of medical gases in the patient's upper airways without the need to insert any additional devices in the trachea.
VALIDITY DATE OF REGISTRATION	30/12/2021 - 29/12/2026

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	LiteStar Anesthesia Mask size 1	MP11001
2	LiteStar Anesthesia Mask size 2	MP11002
3	LiteStar Anesthesia Mask size 3	MP11003
4	LiteStar Anesthesia Mask size 4	MP11004
5	LiteStar Anesthesia Mask size 5	MP11005
6	LiteStar Anesthesia Mask size 6	MP11006

NO	NAME OF DEVICE	IDENTIFIER
7	LiteStar Anesthesia Mask size 7	MP11007
8	Hook ring for LiteStar masks	MP11008
9	Headgear, soft fabric, disposable, small	MP01559
10	Headgear, soft fabric, disposable, large	MP01560
11	Headgear, soft rubber, disposable, small	MP01561
12	Headgear, soft rubber, disposable, large	MP01562



MEDICAL DEVICE AUTHORITY