



DEVICE DETAILS

NAME OF DEVICE	DRAEGER FULL FACE MASK NON-INVASIVE VENTILATION FACE MASKS
ESTABLISHMENT NAME	DRAEGER MALAYSIA SDN BHD
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GB7642222-99649
BRAND NAME	DRAEGER
MEDICAL DEVICE CATEGORY	MD 0101 - Non-active devices for anaesthesia, emergency and intensive care
DEVICE GROUPING TYPE	FAMILY
DEVICE DESCRIPTION	The mask is designed for noninvasive ventilation therapy. As the mask covers nose and mouth, it provides an effective therapy, even in case of mouth breathing.



MEDICAL DEVICE AUTHORITY

DEVICE INTENDED PURPOSE

ClassicStar The ClassicStar NIV nasal masks and ClassicStar plus NIV nasal masks, non-vented or vented, are intended to provide a patient interface for adult patients (>30 kg/66 lb) who are appropriate candidates for non-invasive ventilation in hospital environments. The masks are intended to be used as accessories to ventilators that have appropriate alarms and safety systems for ventilator failure. The masks are intended to administer CPAP (Continuous Positive Airway Pressure/spontaneous breathing with continuous positive airway pressure) or mechanical ventilation for treatment of respiratory insufficiency/disorder. The NIV nasal masks are disposable masks for single-patient use. The ClassicStar NIV oronasal masks are intended as patient interface for adults (>30 kg/66 lb) who are appropriate candidates for non-invasive ventilation in hospital environments, also during transport, or in vehicles, helicopters, and airplanes during emergency situations. The NIV oronasal masks are disposable masks for single-patient use. ClassicStar NIV total-face mask with standard elbow (SE) The NIV total-face mask ClassicStar SE, non-invasive ventilation (NIV), with standard elbow (SE), is intended to provide a patient interface for application of non-invasive ventilation. The NIV total-face mask is to be used as an accessory to ventilators that have appropriate alarms and safety systems for ventilator failure and which are intended to administer continuous positive airway pressure (CPAP) or positive pressure ventilation for treatment of respiratory failure or respiratory insufficiency. It is intended for application on adults (>30 kg/66 lbs) who are appropriate candidates for non-invasive ventilation in hospital or institutional environments. The ClassicStar NIV total-face masks are for single-patient use. ClassicStar NIV total-face mask with anti-asphyxia valve (AAV) The NIV total-face mask ClassicStar AAV, non-invasive ventilation (NIV), with anti-asphyxia valve (AAV), is intended to be used with positive airway pressure devices (PAP devices), operating at or above 3 hPa (3 cmH₂O). The NIV total-face mask has exhalation ports and therefore does not require the use of a separate exhalation device. It is intended for application on adults (>30 kg/66 lbs) who are appropriate candidates for non-invasive ventilation in hospital or institutional environments. ClassicStar NIV total-face mask with anti-asphyxia valve (AAV) without exhalation ports (EP) The NIV total-face mask ClassicStar AAV without EP, non-invasive ventilation (NIV), with anti-asphyxia valve (AAV) and without exhalation ports (EP), is intended to be used with positive airway pressure devices (PAP devices), operating at or above 3 hPa (3 cmH₂O). The NIV total-face mask has no exhalation ports and therefore the connection of an external exhalation system is absolutely required. It is intended for application on adults (>30 kg/66 lbs) who are appropriate candidates for non-invasive ventilation in hospital or institutional environments. The ClassicStar NIV total-face masks are for single-patient use. NovaStar The NovaStar NIV oronasal mask can be used multiple times on multiple patients. Reuse, however, is limited to a maximum of 5 times. It is intended for application on adults (>30 kg/66 lb) who are appropriate candidates for non-invasive ventilation in hospital environments. NovaStar plus SE The NovaStar plus NIV oronasal mask with standard elbow (SE) is intended to provide a patient interface for the application of non-invasive ventilation. The mask is intended to be used as accessory to ventilators that have appropriate alarms and safety systems for ventilator failure. The mask is intended to administer CPAP (Continuous Positive Airway Pressure/spontaneous breathing with continuous positive airway pressure) or mechanical ventilation for treatment of respiratory failure or respiratory insufficiency. NovaStar plus AAV The NovaStar plus NIV oronasal mask with anti-asphyxia valve (AAV) is intended to be used with positive airway pressure devices (PAP devices) operating at or above 3 hPa (3 cmH₂O). The mask has exhalation ports and therefore does not require the use of a separate exhalation device. NovaStar plus AAV without EP The NovaStar plus NIV oronasal mask with anti-asphyxia valve (AAV) without EP is intended to be used with positive airway pressure devices (PAP devices) operating at or above 3 hPa (3 cmH₂O). The mask has no exhalation ports and therefore the connection of an external exhalation device is absolutely required. Because the family of masks used with different accessories end up in different design, causing the use of the masks has slight difference. Please refer to the Intended use in the Annex E IFU and Intended use document.

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	ClassicStar® NIV, Full Face Mask, AAV, Size S	MP01570
2	ClassicStar® NIV, Full Face Mask, AAV, Size M	MP01571
3	ClassicStar® NIV, Full Face Mask, AAV, Size L	MP01572
4	ClassicStar® NIV, Full Face Mask, SE, Size S	MP01573
5	ClassicStar® NIV, Full Face Mask, SE, Size M	MP01574
6	ClassicStar® NIV, Full Face Mask, SE, Size L	MP01575
7	Sizing gauge for ClassicStar NIV oronasal masks	MP01592
8	NovaStar® NIV, Full Face Mask, SE, Size S	MP01579
9	NovaStar® NIV, Full Face Mask, SE, Size M	MP01580
10	NovaStar® NIV, Full Face Mask, SE, Size L	MP01581
11	NovaStar® NIV, Full Face Mask, AAV, Size S	MP01576
12	NovaStar® NIV, Full Face Mask, AAV, Size M	MP01577
13	NovaStar® NIV, Full Face Mask, AAV, Size L	MP01578
14	Headgear for NovaStar™ NIV, Full Face Mask, SE	MP01583
15	Headgear for NovaStar™ NIV, Full Face Mask, AAV	MP01584
16	ClassicStar® NIV, Nasal Mask, vented, Size S	MP01620
17	ClassicStar® NIV, Nasal Mask, vented, Size M	MP01621
18	ClassicStar® NIV, Nasal Mask, vented, Size L	MP01622
19	ClassicStar® NIV, Nasal Mask, non- vented, Size S	MP01623
20	ClassicStar® NIV, Nasal Mask, non- vented, Size M	MP01624
21	ClassicStar® NIV, Nasal Mask, non- vented, Size L	MP01625
22	Sizing gauge for ClassicStar NIV nasal masks	MP01632

NO	NAME OF DEVICE	IDENTIFIER
23	NovaStar SE Vpack S, 3 x MP01579	MP01564
24	NovaStar SE Vpack M, 3 x MP01580	MP01565
25	NovaStar SE Vpack L, 3 x MP01581	MP01566
26	NovaStar SE Vpack S, 3 x MP01576	MP01567
27	NovaStar SE Vpack M, 3 x MP01577	MP01568
28	NovaStar SE Vpack L, 3 x MP01578	MP01569
29	ClassicStar, NIV total-face mask, Standard elbow, single patient use, size S	MP02910
30	ClassicStar, NIV total-face mask, Standard elbow, single patient use, size M	MP02911
31	ClassicStar, NIV total-face mask, Standard elbow, single patient use, size L	MP02912
32	ClassicStar, NIV total-face mask, Anti-Asphyxia Valve, single patient use, S	MP02913
33	ClassicStar, NIV total-face mask, Anti-Asphyxia Valve, single patient use, M	MP02914
34	ClassicStar, NIV total-face mask, Anti- Asphyxia Valve, single patient use, L	MP02915
35	ClassicStar, NIV total-face mask, AAV, w/o exh. ports, single patient use, S	MP02916
36	ClassicStar, NIV total-face mask, AAV, w/o exh. ports, single patient use, M	MP02917
37	ClassicStar, NIV total-face mask, AAV, w/o exh. ports, single patient use, L	MP02918
38	NovaStar TS NIV-Mask, AAVNV, S	MP04701
39	NovaStar TS NIV-Mask, AAVNV, M	MP04702
40	NovaStar TS NIV-Mask, AAVNV, L	MP04703
41	NovaStar TS NIV-Mask, AAVNV, XL	MP04704
42	NovaStar TS NIV-Mask, SE, XL	MP04705
43	NovaStar TS NIV-Mask, AAV, XL	MP04706
44	ClassicStar plus NIV oronasal mask with SE, size S	MP04711
45	ClassicStar plus NIV oronasal mask with SE, size M	MP04712
46	ClassicStar plus NIV oronasal mask with SE, size L	MP04713
47	ClassicStar plus NIV oronasal mask with SE, size XL	MP04714
48	ClassicStar plus NIV oronasal mask with AAV, size S	MP04721

NO	NAME OF DEVICE	IDENTIFIER
49	ClassicStar plus NIV oronasal mask with AAV, size M	MP04722
50	ClassicStar plus NIV oronasal mask with AAV, size L	MP04723
51	ClassicStar plus NIV oronasal mask with AAV, size XL	MP04724
52	ClassicStar plus NIV oronasal mask with AAV without EP, size S	MP04731
53	ClassicStar plus NIV oronasal mask with AAV without EP, size M	MP04732
54	ClassicStar plus NIV oronasal mask with AAV without EP, size L	MP04733
55	ClassicStar plus NIV oronasal mask with AAV without EP, size XL	MP04734
56	Sizing gauge for ClassicStar plus NIV oronasal mask	MP04795
57	ClassicStar plus NIV nasal mask non vented, single patient use, size S	MP04741
58	ClassicStar plus NIV nasal mask non vented, single patient use, size M	MP04742
59	ClassicStar plus NIV nasal mask non vented, single patient use, size L	MP04743
60	ClassicStar plus NIV nasal mask non vented, single patient use, size XL	MP04744
61	ClassicStar plus NIV nasal mask vented, single patient use, size S	MP04751
62	ClassicStar plus NIV nasal mask vented, single patient use, size M	MP04752
63	ClassicStar plus NIV nasal mask vented, single patient use, size L	MP04753
64	ClassicStar plus NIV nasal mask vented, single patient use, size XL	MP04754
65	Sizing gauge for ClassicStar plus NIV nasal mask	MP04796
66	NovaStar plus, NIV mask, SE, S	MP05051
67	NovaStar plus, NIV mask, SE, M	MP05052
68	NovaStar plus, NIV mask, SE, L	MP05053
69	NovaStar plus, NIV mask, SE, XL	MP05054
70	NovaStar plus, NIV mask, AAV, S	MP05061
71	NovaStar plus, NIV mask, AAV, M	MP05062
72	NovaStar plus, NIV mask, AAV, L	MP05063
73	NovaStar plus, NIV mask, AAV, XL	MP05064
74	NovaStar plus, NIV mask, AAVnV, S	MP05071

NO	NAME OF DEVICE	IDENTIFIER
75	NovaStar plus, NIV mask, AAVnV, M	MP05072
76	NovaStar plus, NIV mask, AAVnV, L	MP05073
77	NovaStar plus, NIV mask, AAVnV, XL	MP05074
78	NovaStar plus Headgear	MP05080
79	Sizing gauge	MP05081
80	Clips, Set of 4	MP01585
81	Sizing Gauge ClassicStar nasal mask	8714789
82	Sizing Gauge ClassicStar Full Face mask	8714586
83	Sizing Gauge ClassicStar Total Face mask	MP02919
84	Two-side pump ball for air management	MP01590



MEDICAL DEVICE AUTHORITY