



## DEVICE DETAILS

NAME OF DEVICE	PERFORMAX PEDIATRIC SE TOTAL FACE MASK
ESTABLISHMENT NAME	PHILIPS MALAYSIA SDN BERHAD
REGISTRATION NO	GB821231357119
BRAND NAME	PHILIPS RESPIRONICS
DEVICE GROUPING TYPE	FAMILY
DEVICE DESCRIPTION	<p>THE PERFORMAX PEDIATRIC SE TOTAL FACE MASK IS INTENDED TO PROVIDE A PATIENT INTERFACE FOR APPLICATION OF NONINVASIVE VENTILATION WHEN USED AS AN ACCESSORY TO VENTILATORS WHICH HAVE ADEQUATE ALARMS AND SAFETY SYSTEMS FOR VENTILATOR FAILURE AND WHICH ARE INTENDED TO ADMINISTER CPAP OR POSITIVE PRESSURE VENTILATION FOR TREATMENT OF RESPIRATORY FAILURE, RESPIRATORY INSUFFICIENCY, OR OBSTRUCTIVE SLEEP APNEA. IT PROVIDES A SEAL SUCH THAT POSITIVE PRESSURE FROM THE POSITIVE PRESSURE SOURCE IS DIRECTED INTO THE PATIENT'S NOSE AND MOUTH. IT IS HELD IN PLACE WITH AN ADJUSTABLE BONNET HEADGEAR. IT MAY BE CLEANED BY THE PROFESSIONAL IN THE HOSPITAL/INSTITUTIONAL ENVIRONMENT THROUGH A THERMAL HIGH-LEVEL DISINFECTION PROCESS OR A CHEMICAL HIGH LEVEL DISINFECTION PROCESS FOR MULTI-PATIENT USE. THE PERFORMAX PEDIATRIC SE TOTAL FACE MASK CONSISTS OF A FACEPLATE WITH A BONDED SILICONE SEAL FOR THE FACE. A 22 MM STANDARD ELBOW IS CONNECTED TO THE ELBOW HUB ON THE FACEPLATE. THE 22 MM ELBOW IS USED TO CONNECT A CONVENTIONAL AIR DELIVERY HOSE BETWEEN THE MASK AND THE POSITIVE AIRWAY PRESSURE SOURCE. THE BONNET HEADGEAR IS CONNECTED TO THE MASK THROUGH SLOTS IN THE UPPER PART OF THE FRAME AND CLIPS THAT ATTACH TO THE LOWER PART OF THE FRAME. THE MASK IS DESIGNED IN SUCH A WAY THAT IT CAN BE EASILY DISASSEMBLED FOR DISINFECTION OR TO REPLACE SEVERAL OF THE MASK COMPONENTS, SUCH AS THE HEADGEAR AND ELBOW.</p>
DEVICE INTENDED PURPOSE	<p>THE PERFORMAX PEDIATRIC SE TOTAL FACE MASK IS INTENDED TO PROVIDE A PATIENT INTERFACE FOR APPLICATION OF NONINVASIVE VENTILATION. THE MASK IS TO BE USED AS AN ACCESSORY TO VENTILATORS WHICH HAVE ADEQUATE ALARMS AND SAFETY SYSTEMS FOR VENTILATOR FAILURE, AND WHICH ARE INTENDED TO ADMINISTER CPAP OR POSITIVE PRESSURE VENTILATION FOR TREATMENT OF RESPIRATORY FAILURE, RESPIRATORY INSUFFICIENCY, OR OBSTRUCTIVE SLEEP APNEA. THE MASK IS FOR SINGLE USE/MULTIPLE USE IN THE HOSPITAL/INSTITUTIONAL ENVIRONMENT ONLY. THE MASK IS TO BE USED ON PATIENTS 1 YEAR OR OLDER (&gt;7 KG) WHO ARE APPROPRIATE CANDIDATES FOR NONINVASIVE VENTILATION.</p>
VALIDITY DATE OF REGISTRATION	05/08/2019 - 04/08/2024

## LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	XXS PerforMax SE, MPU with 4 headgear [2 pink, 2 blue]	1083086
2	XS PerforMax SE, MPU with 4 headgear [2 pink, 2 blue]	1083085
3	XXS PerforMax SE, SU with headgear [Yellow]	1083150
4	XS PerforMax SE, SU with headgear [Yellow]	1083149
5	Headgear Bonnet with clips PerforMax XS/XXS Pediatric 6 Pack [3 Pink, 3 Blue]	1083152
6	Headgear Bonnet with clips PerforMax XS/XXS Pediatric 6 Pack [Yellow]	1097304
7	Headgear Bonnet with clips Petite PerforMax Pediatric [Yellow] 6 Pack	1101910
8	Headgear Bonnet with clips Petite PerforMax Pediatric [3 Pink, 3 Blue] 6 Pack	1101909
9	Sizing Gauge PerforMax XS/XXS Pediatric, 25 Pack	1083153
10	CleanClip Shell XS PerforMax, 9 Pack	1099040
11	CleanClip Shell XXS PerforMax, 9 Pack	1099041
12	EE Leak 1 Elbow, for PerforMax XS/XXS Mask, 5 Pack	1100688
13	Bronchoscopy Elbow, Single	1072651
14	Bronchoscopy Elbow, 5 Pack	1072652

