



## DEVICE DETAILS

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| <b>NAME OF DEVICE</b>                | PISTON COMPRESSOR NEBULIZER   |
| <b>ESTABLISHMENT NAME</b>            | PFLEGE MEDICAL SUPPLIES SDN. BHD.   |
| <b>ROLE OF ESTABLISHMENT</b>         | AUTHORIZED REPRESENTATIVE   |
| <b>REGISTRATION NO</b>               | GB4675923-120945  |
| <b>BRAND NAME</b>                    | PROFIX  |
| <b>MEDICAL DEVICE CATEGORY</b>       | MD 1100 - GENERAL ACTIVE MEDICAL DEVICES  |
| <b>DEVICE GROUPING TYPE</b>          | SYSTEM  |
| <b>DEVICE DESCRIPTION</b>            | PROFIX Piston Compressor Nebulizer is a medical device designed to deliver medication prescribed by physician to the airways of the lungs. The nebulizer and air compressor combined provides an aerosol mist for inhalation by the patient for medical treatment only. PROFIX Piston Compressor Nebulizer consists of the following items: • 1x Main Device(Compressor) • 1x Aerosol Nebulizer • 1x Aerosol Tubing • 1x Mask(Adult&Child) • 1x Mouth Piece |
| <b>DEVICE INTENDED PURPOSE</b>       | PROFIX Piston Compressor Nebulizer is intended for use in the treatment of asthma, COPD and other respiratory ailments in which an aerosolized medication is required during therapy. The device is for pediatric and adult population, and it should be used under the supervision of a licensed physician and/or a respiratory therapist.   |
| <b>VALIDITY DATE OF REGISTRATION</b> | 24/02/2023 - 23/02/2028   |

## LIST OF DEVICE

| NO | NAME OF DEVICE              | IDENTIFIER |
|----|-----------------------------|------------|
| 1  | Piston Compressor Nebulizer | NB-P1      |