



DEVICE DETAILS

NAME OF DEVICE	COMPRESSOR NEBULIZER
ESTABLISHMENT NAME	REVO HEALTHCARE SDN BHD
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GB7927519-38132
BRAND NAME	A&D
MEDICAL DEVICE CATEGORY	MD 1102 - Respiratory devices, including hyperbaric chambers for oxygen therapy, inhalation anaesthesia
DEVICE GROUPING TYPE	SYSTEM
DEVICE DESCRIPTION	<p>The A&D Compressor Nebulizer UN-014 is designed to deliver a prescribed medication solution to treat patient respiratory disorder; such as asthma, allergies and bronchitis. The nebulizer converts the medication solution into an aerosolized mist which is inhaled by the patient through the mouth piece or mask. It produces low noise level of only 58dB with particle size of approximately 3µm. Its maximum nebulizer solution capacity is 6ml and its liter flow range is 5-8 L/min. It consists of a comprehensive set of accessories: inhalation with mask or mouthpiece which is ideal for children or adult. The A&D Compressor Nebulizer UN-014 and BR-CN116 Mini Compressor Nebulizer are identical in terms of the technical specifications, intended purpose and accessories used. Kindly refer to the declaration and consent letter from the manufacturer attached in 4.0 CSdT.</p>
DEVICE INTENDED PURPOSE	<p>The A&D Compressor Nebulizer UN-014 is designed to deliver a prescribed medication solution to treat patient respiratory disorder; such as asthma, allergies and bronchitis.</p>
VALIDITY DATE OF REGISTRATION	19/12/2019 - 18/12/2024

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	Compressor Nebulizer UN-014	UN-014
2	Adult mask	UNB-014A-01EC
3	Child mask	UNB-014A-02EC
4	Air tube	UNB-014A-03EC
5	Air filter	UNB-014A-04EC
6	Nebulizer cup	UNB-014A-05EC
7	Mouth piece	UNB-014A-06EC