



PIHAK BERKUASA PERANTI  
PERUBATAN  
Medical Device Authority  
KEMENTERIAN KESIHATAN MALAYSIA  
Ministry of Health Malaysia  
Level 6, Prima 9, Prima Avenue II  
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Ref No : (14) dlm. MDA. 600-1/6/1 01d 14/  
Date : 20 May 2022

**American Air Filter Manufacturing Sdn. Bhd.**  
Lot 6, Jln Pengapit 15/19,  
Seksyen 15,  
40000 Shah Alam,  
Selangor.  
(attn: Mr. Lee Lin Jeat)

Sir/Madam,

**INQUIRY TO DETERMINE WHETHER A PRODUCT IS A MEDICAL DEVICE**  
**REF: MDA/PC/2022/151**

With reference to the above, the following product **shall not be** considered as a medical device in accordance with medical device definition as specified in Section 2, of the Medical Device Act 2012 (Act 737).

**Name of the Product : ASTROPure™ 550C (Portable Air Purifier)**

Description of the product : Refer Attachment 1

Intended Use of the product : Refer Attachment 1

Address of the Manufacturer : **American Air Filter Manufacturing Sdn. Bhd.**  
Lot 6, Jln Pengapit 15/19, Seksyen 15, 40000 Shah Alam, Selangor.

2. Any product that falls within the definition of "medical device" under the provision of section 2 of Act 737 shall be registered under section 5(1) of the Act. Advertising of unregistered medical device is an offence under Section 44, Act 737. Any individual who commits an offence under this section can be fined up to a maximum of RM 300 000 or 3 years imprisonment or both.

3. This letter is based on the information submitted by the applicant and **ONLY** for product classification purpose. This letter is revoked if there are modifications to the intended purpose submitted during the application and subject to policy changes from time to time.

4. This letter **DOES NOT CONSTITUTE AN APPROVAL** for the product and shall not be used for the purpose of promoting or advertising the product.

Thank you.

  
**AHMAD SHARIFF BIN HAMBALI**  
Chief Executive  
Medical Device Authority  
Ministry of Health, Malaysia



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**Attachment 1**

No.	Name of the Product	Description of the Product	Intended Use of the Product
1.	<b>ASTROPure™ 550C</b> <b>(Portable Air Purifier)</b>	ASTROPure™ 550C provides safer and cleaner air, as the system is designed to operate with 4 stages of air filtration that is effective in purifying the polluted air, such as pollen, haze, fine dust, harmful gases and odours, and even the health threatening microorganisms. ASTROPure™ 550C can be connected with a mobile devices to remotely control and monitor the indoor air quality. It is equipped with the advance sensors to monitor the indoor air quality accurately and to ensure that the air you breathe is safe and clean. User friendly, just switch it ON and it will automatically adjust its fan speed accordingly to indoor air quality by the sensors.	Air Purifier with H14 True HEPA Filter. Effectively removes up to 99.995% of ultra-fine particles and the use of UVC energy to inactivate viral, bacterial, and fungal organisms, improving indoor air quality in home and residential buildings, offices and buildings, cinemas, schools, clinics and hospitals, malls, stores, and commercial spaces, hotel and resorts, saloon and spas.

