



PIHAK BERKUASA PERANTI PERUBATAN
Medical Device Authority
KEMENTERIAN KESIHATAN MALAYSIA
Ministry of Health Malaysia
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Ref No : (17) dlm. MDA. 600-1/6/1 7LD84
Date : 8 April 2020

Antah Pharma Sdn Bhd
3, Jalan 19/1,
46300 Petaling Jaya
Selangor
(attn: Ms Madeline Oon)

Sir/Madam,

INQUIRY TO DETERMINE A PRODUCT WHETHER IS A MEDICAL DEVICE
REF: MDAPC2020116

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 : a+ Defend

Description of the product : A wellness health tag which can be worn up to 45 days protection and within 1 m³. This product contain sodium chlorite (NaClO₂) powder.

Intended use of the product : To protect from air-borne diseases that releases anti-microbial chlorine dioxide

Address of the Manufacturer : Cleancare Co., Ltd
3-1-14 Kawaguchi, Nishi-ku, Osaka, Japan

2. Any product that falls within the provision of section 2 of "medical device" shall be registered under section 5(1) of the Act 737.

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