



ARAM HUVIS Co., Ltd.

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Reference : A00513-15

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DECLARATION OF NON-MEDICAL DEVICE

Because this device (API) is not for monitoring, diagnosing, and curing patients, it is not applicable to EN 60601 Medical devices directive.

A handwritten signature in black ink, appearing to be 'CW' or 'Chang Won'.

Chang Won Kim / Manager

Ministry of Food and Drug Safety

Aram HUVIS Co., Ltd. 801 Byucsan Technopia, 560, Dunchon-daero, Jungwon-gu, Sunghamsi, Kyunggido, South Korea(zip code 462-716)

Title : Reply of reviewing whether it is medical device or not.

1. The request from your company (Registration Number : 20150070549, 2015.04.21) 'reviewing whether it is medical device or not' related.

2. According to medical device law Article 2 Clause 1, medical device is defined as Appliances, machinery, equipment, materials that are used to people or animals by single or combination or similar products that come under below clauses(Except : Pharmaceuticals, quasi-drugs, orthotics)

- a. Products are used for diagnosis, treatment, mitigation or prevention of disease.
- b. Products are used for diagnosis, treatment, mitigation or correction of disability & injury
- c. Products are used for inspection, replacement and strain structure or feature.
- d. Products are used for pregnancy control

3. The product that you inquiry is 'The camera device to capture skin for cosmetic recommendation. Not the purpose to diagnose or treat the disease'. According to the medical device law article 2, we kindly inform that **it is not a medical device**.

4. [Medical device law] article 26, 'Whatever if the device is not the medical device, it is not allowed to advertise that it has the similar function or effect as a medical device and mark that could cause the misunderstanding in the package, surface or attached documents. Please note that if you sell, rent these kind of marked devices, according to the same clause, it could be punished.

5. For reference, to judge accurately it is the medical device or not according to medical device law article 2 clause 1, if it is using for the purpose of above explanation, then it is considered as it is

not a medical device. Also it does not need to have objectively this kind of function. And the device usage purpose should be defined by total consideration of devices structure, shape, marked usage purpose and effect, advertisement and explanation(supreme court 2010.4.29 declare 2008.7688 judgment, supreme court 1993.3.12 declare 92.811 judgment.). It is declared.

6. If you have any further questions, please contact(Jiyoung Park, Medical equipment policy department, +82 43 230 0421). Then we will kindly guide. End.