



30 APR 2019

**FDA ADVISORY**  
No. **2019-113**

**TO :** **ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC**

**SUBJECT :** **Public Health Warning Against the Purchase and Use of Unregistered Medical Device “Cofoe Forehead Infrared Thermometer” advertised for sale in Shopee website**

The Food and Drug Administration (FDA) advises the general public and all healthcare professionals against the purchase and use of the unregistered medical device:

**05**  
COFOE

**Infrared rapid temperature measurement**  
Passive infrared temperature measurement technology, no radiation measurement for 1 second,  
And avoid contact with baby's skin, causing infection

**Radiation-free**

1s

Figure 1. Cofoe Forehead Infrared Thermometer





Figure 2. Cofoe Forehead Infrared Thermometer

PRODUCT INFORMATION			
Brand	Cofoe	Product Name	Cofoe Non-contact IR Digital
Model No	HTD8818D	Battery	DC3V,2*AAA Alkaline Battery
Memory	50 sets	Size	138*95*40mm
Measurement time	≤2 second	Weight	90g
Measurement error	± 0.1- ± 0.3 degrees Celsius		
Measurement Range	34-42.9		
Automatic shutdown	≤18 second		
Measurement Distance	1-3cm		
Different Color	Backlight with Three Different Color Green:34-37.3 Orange:37.4-38.0    Red:38.1-42.9		

### Battery installation

It is important to install the battery like image!

Figure 3. Cofoe Forehead Infrared Thermometer

FDA post-marketing surveillance (PMS) activities have verified that the abovementioned medical device has not gone through the registration process of the agency and has not been issued with proper authorization in the form of Certificate of Product Registration (CPR). Pursuant to Republic Act 9711, otherwise known as the "Food and Drug Administration Act of 2009", the manufacture, importation, exportation, sale, offering for sale, distribution, transfer, non-consumer use, promotion, advertising or sponsorship of health products without the proper authorization from FDA is prohibited.

Accordingly, since this unregistered medical device has not gone through evaluation and testing process of the FDA, the agency cannot guarantee its quality and safety. The consumption of such violative product may pose potential health hazards to the consuming public.

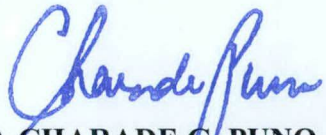
In light of the above, the public is advised not to purchase this and to be vigilant against medical device that might not be duly registered with FDA. Always check if a medical device has been registered with the FDA before purchasing it by making use of the embedded *Search* feature of the FDA website accessible at [www.fda.gov.ph](http://www.fda.gov.ph).

All concerned establishments and/or entities are warned not to distribute the above-identified violative medical devices product until he has already been covered by the appropriate authorization, otherwise, regulatory actions and sanctions shall be strictly pursued.

All Local Government Units (LGUs) and Law Enforcement Agencies (LEAs) are requested to ensure that this product is not sold or made available in their localities or areas of jurisdiction.

For more information and inquiries, please e-mail us at [info@fda.gov.ph](mailto:info@fda.gov.ph). To report continuous sale or distribution of the above unregistered medical device, utilize our online reporting facility, **eReport**, at [www.fda.gov.ph/ereport](http://www.fda.gov.ph/ereport), or e-mail us via [report@fda.gov.ph](mailto:report@fda.gov.ph), or call us at the Center for Device Regulation, Radiation Health and Research (CDRRHR) hotline **(02) 857-1900 local 8301**.

Dissemination of the information to all concerned is requested.

  
**NELA CHARADE G. PUNO, RPh**  
Director General

**DTN: 20190223104143**