

18 APR 2024

FDA ADVISORY

No. 2023-1946-A

TO: ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC

SUBJECT: Lifting of the FDA Advisory No. 2023-1946 entitled Public Health Warning Against the Purchase and Use of the Unregistered Medical Device Product "ICARE® INFRARED THERMOMETER"

The Food and Drug Administration (FDA) informs all healthcare professionals and the general public that the medical device product, iCARE® Infrared Thermometer, has been issued an FDA Certificate of Medical Device Registration (CMDR) to the Market Authorization Holder (MAH), Aviton Enterprises, in accordance with the existing FDA rules and regulations.

Accordingly, the warning against the purchase and use of the product as mentioned in FDA Advisory No. 2023-1946 dated September 19, 2023, is hereby lifted.

The issuance of this advisory shall not in any manner preclude this Office from issuing subsequent orders it may deem necessary and appropriate, should there be findings of any violation of the company to existing laws, rules, and regulations.

For more information and inquiries, kindly contact the FDA Center for Device Regulation, Radiation Health, and Research through e-mail at cdrhr@fda.gov.ph or call (02) 8857-1900 loc. 8301.

To report any sale or distribution of unregistered medical device, contact the online reporting facility, **eReport**, through e-mail at ereport@fda.gov.ph.

Dissemination of this advisory to all concerned is hereby requested.


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Director General

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