Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA Food and Drug Administration PHILIPPINES

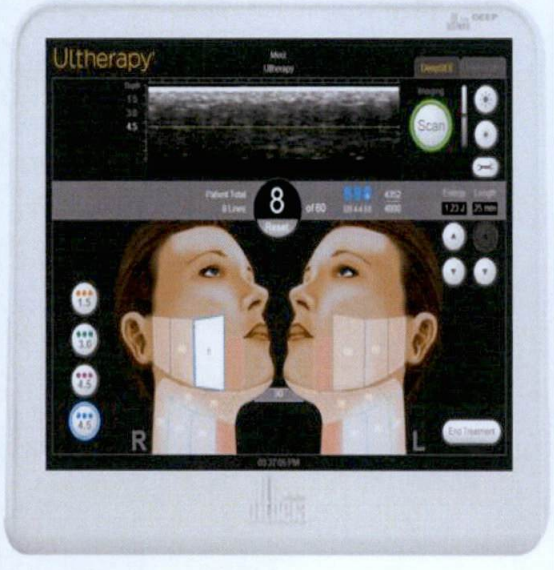
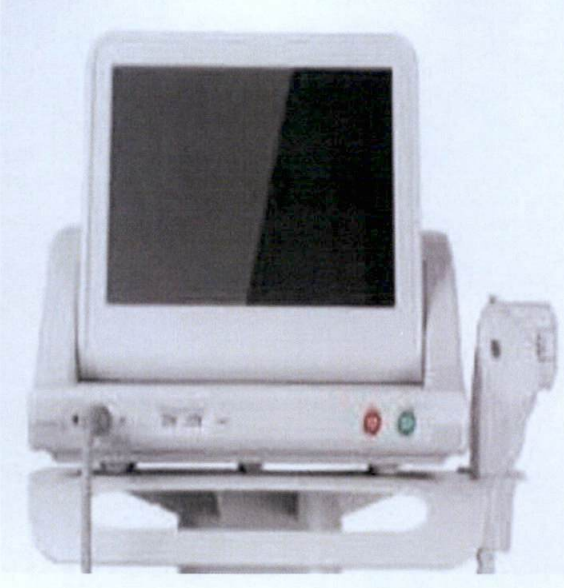
09 MAR 2023

FDA ADVISORY
No.: 2023-0364

TO: **ALL HEALTHCARE PROFESSIONALS AND ESTABLISHMENTS**

SUBJECT: **Public Health Warning Against the Purchase and Use of Counterfeit Medical Device "Ulthera® System"**

The Food and Drug Administration (FDA) warns all healthcare professionals and the general public against the purchase and use of the counterfeit version of Ulthera® System. Please see particulars/details of the original vs. the counterfeit products as provided below:

ORIGINAL	COUNTERFEIT
 FRONT	

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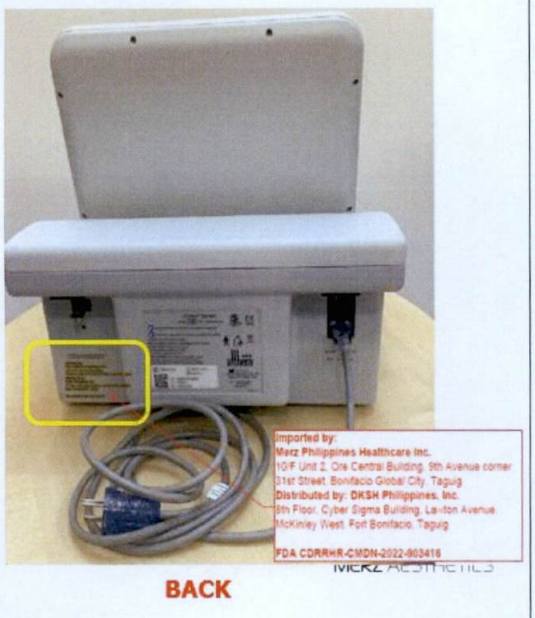


Figure 1. Photo of the Original FDA Notified vs Counterfeit Ulthera® System Control Unit

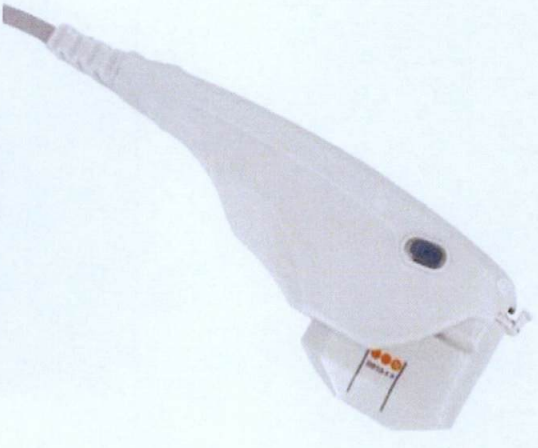
ORIGINAL	COUNTERFEIT
	

Figure 2. Photo of the Original FDA Notified vs Counterfeit Ulthera® System Handpiece

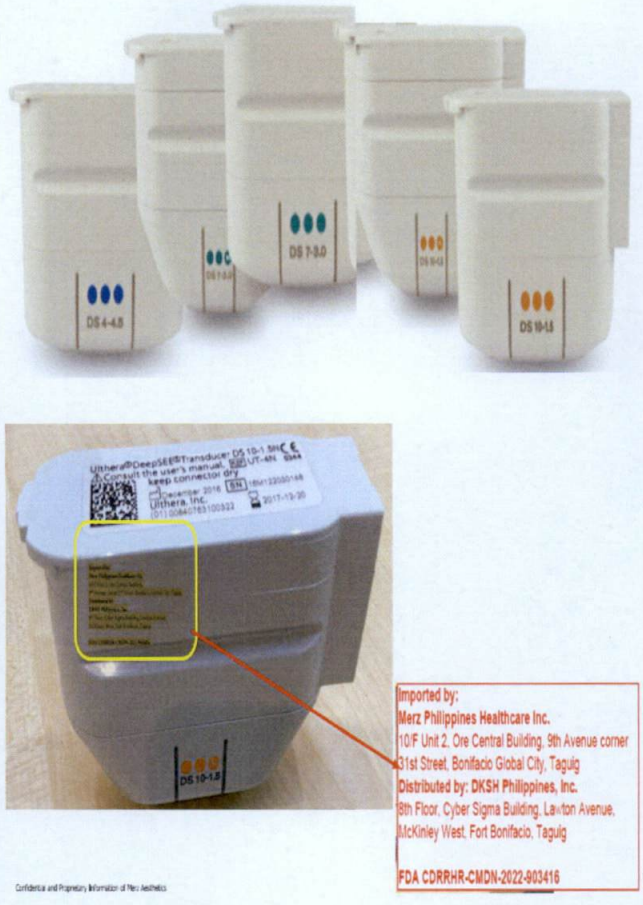
ORIGINAL	COUNTERFEIT
	

Figure 3. Photo of the Original FDA Notified Ulthera® System Transducer vs Counterfeit

The Market Authorization Holder (MAH), Merz Philippines Healthcare Inc., reported to the FDA that the aforementioned medical devices are counterfeit and that there are no approved refurbishers of the said product.

In light of the foregoing, the public is advised not to purchase the aforementioned violative product. These products may pose potential health hazards to the consuming public since its safety and purity cannot be guaranteed.

All concerned establishments are warned not to distribute, the said counterfeit medical devices system.

All FDA Regional Offices and Regulatory Enforcement Unit in coordination with law enforcement agencies and Local Government Units are requested to ensure that this violative product is not sold or made available in the market or their areas of jurisdiction.

The Bureau of Customs is urged to restrain the entry of this counterfeit product.

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

To report any sale or distribution of unregistered medical device, the online reporting facility, **eReport** can be accessed at **www.fda.gov.ph/ereport**.

Dissemination of this advisory to all concerned is hereby requested.

DR. SAMUEL A. ZACARTE
Director General

DTN 20220608073245