Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

15 SEP 2020

FDA ADVISORY
No. 2020-1691

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

SUBJECT: **Public Health Warning Against the Purchase and Use of the Unregistered Medical Device Products:**

1. **NIPRO SYNTHETIC HOLLOW FIBER DIALYZER ELISIO™ 190HR**
2. **NIPRO ELISIO™ - 17H SYNTHETIC HOLLOW FIBER POLYNEPHRON™**

The Food and Drug Administration (FDA) warns all healthcare professionals and the general public **NOT TO PURCHASE AND USE** the unregistered medical device products:

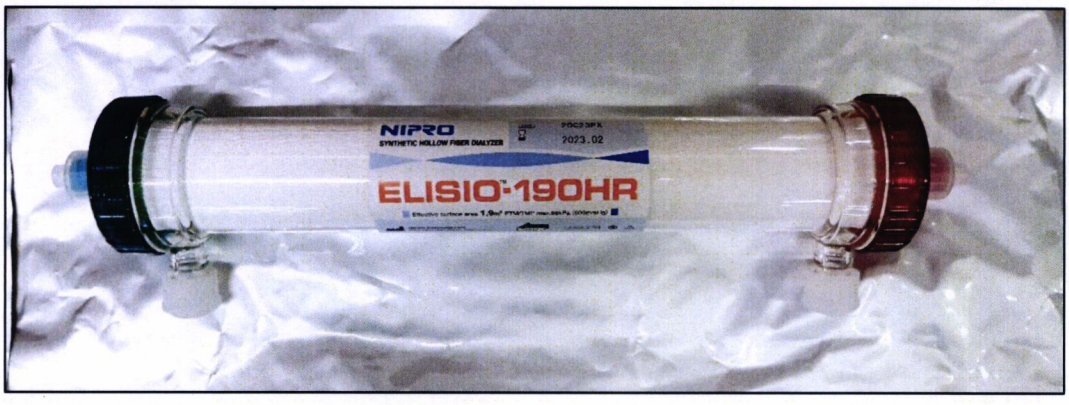

Figure 1. Unregistered NIPRO Synthetic Hollow Fiber Dialyzer Elisio™ 190HR

Figure 2. Unregistered NIPRO Elisio™ - 17H Synthetic Hollow Fiber Polynephron™

The FDA verified through post-marketing surveillance that the above-mentioned medical device products are not registered and no corresponding Product Registration Certificates have been issued. Pursuant to the Republic Act No. 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 is prohibited.

Since these unregistered medical device products have not gone through evaluation process of the FDA, the agency cannot assure its quality and safety.

All concerned establishments are warned not to distribute, advertise, or sell the said violative medical device products until the Product Registration Certificates are issued, otherwise, regulatory actions and sanctions shall be strictly pursued. Always check if a product 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. You may also look for the FDA Registration number on the product label in the form of either DVR-xxx or MDR-xxx.

All Law Enforcement Agencies (LEAs) and Local Government Units (LGUs) are requested to ensure that these products are not sold or made available in the market or areas of jurisdiction.

The Bureau of Customs is urged to restrain the entry of these unregistered products.

For more information and inquiries about this advisory, kindly contact the FDA CDRRHR through e-mail at **cdrrhr@fda.gov.ph** indicating on the subject the concerned Advisory, 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.

ROLANDO ENRIQUE D. DOMINGO, MD
Director General

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