Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY
No. 2020-1691-A

23 DEC 2020

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

SUBJECT: **Lifting of the FDA Advisory No. 2020 – 1691 entitled: Public Health Warning Against the Purchase and Use of the Unregistered Medical Device Product:**

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

The Food and Drug Administration (FDA) informs all healthcare professionals and the general public that the following medical device products have been registered by the Market Authorization Holder, OMM Healthcare Philippines Corporation, in accordance to existing FDA rules and regulations:

1. Nipro Synthetic Hollow Fiber Dialyzer Elisio™ 190HR, with Registration No. MDR-03501
2. Nipro Elisio™ - 17H Synthetic Hollow Fiber Polynephron, with Registration No. MDR-02245

Accordingly, the warning against the purchase and use of the subject medical device products as mentioned in FDA Advisory No. 2020-1691 is hereby lifted.

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 products, the online reporting facility, **eReport** can be accessed at **www.fda.gov.ph/ereport**.

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 the existing laws, rules, and regulations.

Dissemination of this advisory to all concerned is hereby requested.

ROLANDO ENRIQUE D. DOMINGO, MD
Director General

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