Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY
No. 2021-2247-A

22 JUN 2022

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

SUBJECT: **Lifting of the FDA Advisory No. 2021-2247 entitled "Public Health Warning Against the Purchase and Use of the Unregistered Medical Device Product "EVERX FLOW™ SHORT-FIBRE REINFORCED FLOWABLE COMPOSITE FOR DENTIN REPLACEMENT"**

The Food and Drug Administration (FDA) informs all healthcare professionals and the general public that the medical device product, EverX Flow™ Short-Fibre Reinforced Flowable Composite for Dentin Replacement, has been registered by the Market Authorization Holder (MAH), Dental Domain Corporation, with FDA Registration No. CMDR-2022-00598 in accordance to existing FDA rules and regulations.

Accordingly, the warning against the purchase and use of the product as mentioned in FDA Advisory No. 2021-2247 dated 31 August 2021 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 **cdrrhr@fda.gov.ph** or call **(02) 8857-1900 loc. 8301.**

To report any sale or distribution of unnotified 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.

DR. OSCAR G. GUTIERREZ, JR.
Officer-in-Charge Director General

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