



Republic of the Philippines
Office of the President
DANGEROUS DRUGS BOARD

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BOARD RESOLUTION NO. 205
Series of 2013

SUBJECT: GRANTING EXEMPTION FROM SPECIFIC MEASURES OF REGULATORY CONTROL REQUIREMENTS TO CERTAIN FINISHED PRODUCTS OF SYSMEX PHILIPPINES INC.

WHEREAS, under Section 81 (b) and (r) of Article IX of RA 9165, otherwise known as the Comprehensive Dangerous Drugs Act of 2002, the Board issued Board Regulation No. 3, Series of 2003 which provides for the “Comprehensive Guidelines on Importation, Distribution, Manufacture, Prescription, Dispensing and Sale of, and Other Lawful Acts in Connection with any Dangerous Drugs, Controlled Precursors and Essential Chemicals and other Similar or Analogous Substances”;

WHEREAS, SYSMEX PHILIPPINES INC. with business address at 30th Flr. MDC 100E. Rodriguez Jr. Ave. Eastwood Ave., Bagumbayan, Quezon City, Philippines is seeking exemption from regulatory measures for the following products, to wit:

- 1. BILIRUBIN DIRECT (DBIL-R1) – 0.000036% Hydrochloric Acid (HCL)**
- 2. BILIRUBIN DIRECT (DBIL-R2) – 0.00005% Hydrochloric Acid (HCL)**

WHEREAS, Section 4(2-d, e & f), Article II of the same Regulation also provides that the Board may exempt from specific measures of regulatory control requirements any preparation with liquid chemical mixture containing less than 30% by weight of the Table II chemical; or solid, semisolid and highly viscous chemical mixture containing Table II chemical; or when the Board is satisfied that the mixture is formulated in such a way that the controlled chemical cannot be easily used for the illicit manufacture of a dangerous drug and that the controlled chemical or chemicals contained in the mixture cannot be readily recovered;

WHEREAS, Immunoassay Drug test kits were granted exemption by the Board having Board Resolution No. 18, s. 2004 as an example. Considering that this type of reagents/products could not be extracted and contains no or miniscule amount of dangerous drugs/controlled chemicals, thus these products present no or negligible risk of abuse; necessary for medical or scientific purposes and for the interest of the public;

WHEREAS, to assist the Board in evaluating requests for exemption, it promulgated Board Resolution No.1 Series of 2008 entitled “**Creating a Technical Working Group (TWG) to assist the Board in considering request of Manufacturers and Importers of finished products from specific measures of regulatory control requirements**”;

WHEREAS, it has been determined by the DDB Technical Working Group (TWG) that. **SYSMEX PHILIPPINES INC.** has been focusing on healthcare testing business for over 40 years and expanding globally as a leading company in hematology field. The company started its business in 2000 as a local distributor It is duly registered with **PDEA and handler of P5I- 03716001 as importer/distributor. License was issued on February 5, 2013 and valid until 05 February 2014;**

WHEREAS, after due deliberation and evaluation, the TWG decided to recommend to the Board the exemption of **SYSMEX PHILIPPINES INC.** ' finished

products that contain controlled chemicals below the 30% threshold of the Table II chemicals, in accordance with the provisions of Section 4-2(a, b, c, d, e & f);

WHEREAS, after satisfying the requirements stipulated under the above mentioned regulations, **SYSMEX PHILIPPINES INC.**' products are no longer covered by the provisions of Section 10 (Application for import, export or transit permits), and Section 11 (Grant of import, export or transit permits), Section 22 (Licensed operators NOT to deal with unlicensed operators) and of BR No.3, S. 2003.

WHEREFORE, be it **RESOLVED**, as it is hereby **RESOLVED**:

- a. **TO GRANT EXEMPTION** and the issuance of Board Resolution of Exemption, which shall be valid for one (1) year unless revoked, to **SYSMEX PHILIPPINES INC.** products containing controlled chemicals below the 30% threshold of the Table II chemicals, in accordance with the provisions of Section 4-2(d& f).
- b. **That the above cited exemptions shall still be subject to the following conditions:**
 - (1) That **SYSMEX PHILIPPINES INC.** shall secure a license from the PDEA and comply with the reporting requirements for the raw materials used in the manufacture of the products as provided for in Board Regulation No. 3, Series of 2003;
 - (2) The Board shall strictly monitor subject finished products from their manufacture to distribution to end-users;
 - (3) The DDB Monitoring Team shall have free access to **SYSMEX PHILIPPINES INC.** premises where the finished products are kept and/or used;
 - (4) That **SYSMEX PHILIPPINES INC.** shall assume full responsibility for any misuse of the imported finished products, caused either by its own negligence or by negligence of all persons acting under their name or control and supervision; and
 - (5) Any violation of the provisions of Board Regulation No. 3, Series of 2003, shall be a ground for the revocation of the certificate of exemption at anytime and would be dealt with severely.

APPROVED and ADOPTED this 11th day of July, in the year of Our Lord, 2013 in Quezon City.

(Sgd) **Secretary ANTONIO A. VILLAR, JR.**
Chairman, Dangerous Drugs Board

Attested:

(Sgd) **JOSE MARLOWE S. PEDREGOSA**
UNDERSECRETARY-Executive Director
Secretary of the Board

