



Republic of the Philippines  
Department of Health  
**OFFICE OF THE SECRETARY**

02 August 2017

**CERTIFICATION**


This is to certify the one (1) year provisional exemption from Executive Order No. 49 s. 1993 (*Directing the Mandatory Use of the Philippine National Drug Formulary (PNDF) Volume I as the Basis for Procurement of Drug Products by the Government*), effective upon receipt of this certificate, of the following medicine:

Medicine: **Dexmedetomidine hydrochloride 100 mcg/mL, 2 mL vial concentrate for intravenous infusion**

Indication: For sedation of initially intubated and mechanically ventilated patients during treatment in an intensive care setting. For sedation/anxiolysis of non-intubated patients prior to and/or during surgical and other procedures.

The product shall only be utilized by the requesting party – the Philippine Heart Center (PHC). It shall be noted, however, that this exemption shall only be valid provided that the product will be procured at a price not greater than the proposed list price to the government, i.e., **Php 1853.95**. Further, the concerned proponent shall provide the Formulary Executive Council (FEC), through the Pharmaceutical Division, the following documents at the end of exemption validity: (1) local efficacy and safety profile; (2) surveillance report on adverse effects; (3) registry of patients; and (4) impact study/outcomes of patients using the product.

For compliance and strict implementation.

  
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