

Distributing Medical Devices in Indonesia

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As the fourth-most populous country in the world, Indonesia faces many challenges in providing sufficient healthcare services to its nearly 280 million citizens. Among these challenges is a scarcity of medical devices, especially in rural areas. This makes Indonesia a promising market for medical device distribution businesses.

If you are considering distributing medical devices to Indonesia, this article provides a brief overview of the applicable regulatory requirements.

The importing and distribution of medical devices in Indonesia is regulated under Ministry of Health Regulation No. 60 of 2017 on the Supervision of Trade Management for the Import of Medical Devices, In Vitro Diagnostic Medical Devices and Household Medical Supplies (“**MOH Reg. 60/2017**”) and Ministry of Health Regulation No. 62 of 2017 on Distribution Licenses for Medical Devices, In Vitro Diagnostic Medical Devices and Household Medical Supplies, as amended by Ministry of Health Regulation No. 26 of 2018 (“**MOH Reg. 62/2017**”). Under MOH Reg. 62/2017, a distribution license is required for the relevant medical devices. The distribution license for imported medical devices can only be applied for by:

1. a sole agent/sole distributor/exclusive distributor;
2. a medical device distributor with an appointment letter from the principal and a Power of Attorney to register the medical devices in Indonesia;
3. a medical device distributor with an agreement with the manufacturer;

