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A brief for medical device export procedure to Korea.

In order to export medical devices (including SaMD products) to Korea, local laws require that a Korean company be designated as the importer of such medical devices. The importer in this case must also hold 1) a license to import medical devices, 2) product licenses of the imported products, 3) KGMP certification of the manufacturing sites of the medical devices. The Medical Device Act also requires the following procedure when importing medical devices into Korea:

- **Step 1**: The importer of the medical device must prepare a standard customs clearance report to the KMDIA (MFDS assigned organization). At this time, the importer must also submit supporting documentation such as an invoice and product orders, as well as the product licenses.
- **Step 2**: Once the standard customs clearance report is reviewed and approved after Step 1, the importer must also submit a customs report to the Customs Office. The customs office checks whether the reported products are a medical device and will check the supporting documentation to confirm that the imported goods are compliant with Ministry of Food and Drug Safety ("MFDS") requirements.
- **Step 3**: Once the product clears customs, the medical device products must be admitted to a storage facility of the importer entity. And before the medical devices are released for distribution, the products must be checked for quality and the records of such QC must be kept by the importer for at least 5 years. In addition, the QC process can be conducted under DMR (Device Master Record) agreed between the manufacturer and the importer or though GIP (Good Import Practice) procedures.
- **Step 4**: Before the medical device products are released for distribution, the UDI (Unique Device Identification) must be registered with the NIDS (designated agency by the MFDS) and the importer must also produce a report within one month of distribution that lists where the products were supplied (medical institutions or wholesalers etc.).

The MFDS is very active in conducting sampling investigations working in conjunction with the Customs Office to prevent unlicensed products or products with outdated licenses from entering the Korean market. In addition, MFDS officials visit importers often to check on the medical device compliance. For SaMD products, since there are no physical products, Steps 1 and 2 above are exempt. However, Steps 3 and 4 are strictly enforced for SaMD products as well.

Please feel free to contact us at pro@mdrex.co.kr for any questions regarding import procedure or license parking of your medical device products.