Baker McKenzie.

Healthcare
Bangkok

Client Alert
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Reclassifications of Certain Products as High-Risk Medical Devices

For further information, please contact:

Peerapan Tungsuwan
+66 2666 2824 Ext. 4334
peerapan.tungsuwan
@bakermckenzie.com

Prim Uditananda
+66 2666 2824 Ext. 4330
prim.uditananda
@bakermckenzie.com

Three notifications were issued by the Ministry of Public Health to reclassify certain products as high-risk medical devices. These products are **alcohol-based hand sanitizers** with an alcohol concentration of 70% or greater, **injectable hyaluronic acid intended for use as a filler**, and **disinfectants with alcohol as an ingredient intended for use in humans, animals and medical devices**. The notifications were published in the Royal Gazette on 13 September 2019 and will all come into effect 180 days after the publication.

Alcohol-based hand sanitizers and disinfectants with alcohol for use in humans, animals and medical devices will be reclassified as medical devices whose detailed descriptions must be notified to the authority. The obligation to do so falls on manufacturers and importers of these products. Injectable hyaluronic acid will be reclassified as a medical device that requires a license to manufacture, import, and sell. Additionally, according to the notification, injectable hyaluronic acid can only be sold to sanatoriums, medical practitioners, dentists, and licensed medical device distributors.

For more information about how to obtain relevant licenses, please contact us.

www.bakermckenzie.com

Bangkok

5th, 10th and 21st-25th Floors
990 Abdulrahim Place
Rama IV Road, Silom, Bangrak
Bangkok 10500
Thailand