

## How Many FDA Unique Device Identifiers (UDIs) Do I Need?

For a single device type, a separate UDI is needed for each different:  
Size ★ Color ★ Material ★ Style ★ Package Size ★ Etc.

ABC Company manufactures one medical device: Examination Gowns (FDA Product Code: FME)



Each gown comes in three sizes: small, medium, and large



Each size comes in two colors: blue and green



Each gown has two style options: with and without a pocket



And each gown is sold in packages of 50 and 100



ABC Company would need 24 UDIs for its examination gowns.

Contact Registrar Corp for assistance  
with filing your UDIs with the U.S. FDA.  
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