

# Colorcon No-Tox® Medical Device Dye Solution X-1179

## Testing and Verifying the Integrity of your Medical Device Packages

Serving the world's non-toxic printing ink needs for 50 years, Colorcon's No-Tox® Products Division is the leading manufacturer of U.S. Food & Drug Administration (FDA) and E.U. compliant printing inks.

Colorcon's expertise in printing ink technology is based on a solid foundation built over five decades of manufacturing printing inks for the food, medical device and pharma industries.

Our highly specialized No-Tox medical device inks are used for form-fill seal in-line package printing on Tyvek® packaging, product identifications, markings on syringes, pipettes or catheters, and many other applications that directly or indirectly come in contact with the medical device.

Colorcon's X-1179 is a dye based solution concentrate that is specifically designed to test and verify the integrity of medical device packaging seals, a process specified in ASTM F1929-12

Tyvek® is a registered trademark of DuPont™

X-1179 is a dye solution concentrate, that is specifically designed to test and verify the integrity of medical device packaging seals. Specifically, it is designed to test the integrity of sealed edges between a transparent material and a porous sheet material, such as TYVEK®.

X-1179 uses Toluidine-O, an organic compound used in the manufacture of a deep blue dye. The integrity test requires a small amount of the product to be inserted into a sealed sample package container or pouch. The solution then gets slowly rotated around, carefully looking for ink to penetrate/leak through the packaging seals.

This process is specified by the American Society for Testing and Materials as a method to test seals of medical device packages by visually observing the presence of channel defects by the leakage of dye through them (ASTM F1929-12 "Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration").

All products are manufactured under strict cGMP guidelines in our ISO 9001:2015 certified and FDA registered facility.

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