

## **Warning!! The Life Saving Statements**

We tend to see Warning statements as a threat to use the product rather than a reinforcement of protection when using the product. Here, we hope to provide a different perspective to break the stereotype interpretation on WARNING statement.

### ***“Warning: Keep out of reach of children”***

We commonly see this Warning statement on boxes or bottles of healthcare products; including the bottle of multi vitamin syrups that are meant for children.

Would you be interpreting this as the product is unsafe to be consumed by children? The answer is highly NO!

We do not see products with such warning statements when consumed causing harm to our children but as an alert that such products are not safe to be handled or self-administered by children themselves. As a result of such pre-alert, adults will keep the products out of reach of children.

Similarly, medical device products such as examination gloves too would have their fair share of warning statements on the labeling. U.S. FDA imposes stringent needs for proper labeling and instructions especially on medical devices under its regulation in order to provide adequate information for precautional use to us, the consumers. For examination gloves, the mandatory requirement is to ensure there are adequate information on possible related risk and to prevent misleading information on product usage. Full details of Guidance for Industry Presenting Risk Information in Prescription Drug and Medical Device Promotion are easily accessible in the U.S. FDA website.

### ***“This product demonstrated reduced potential for sensitising users to chemical additives.***

### ***Warning: Do not use if you have a known allergy to chemical additives. “***

LOW DERMA™ enhanced nitrile examination glove has been cleared by U.S. FDA with a LOW DERMATITIS POTENTIAL claim. Complementing with the granted claim is a precautionary warning statement that U.S. FDA seeks to alert and to prevent misinterpretation of the claim by consumers, especially those who have had known allergy to chemical additives. Moreover, there is always a possibility of contracting with an allergic reaction even for non-sensitised consumers. However, LOW DERMA™ enhanced nitrile examination glove has been clinically tested and with the LOW DERMATITIS POTENTIAL claim means a LOWER possibility to contract an allergic reactions due to chemical additives.

You may ask, what about those gloves that are without benefit claims such as LOW DERMATITIS POTENTIAL cleared by U.S. FDA, and hence with no regulated needs to have warning statements? Well, without specific “benefit claim”, basically, there is no triggering of misleading information

for consumers to assume; that the gloves DO NOT contain chemical additives NOR having specific benefits of low dermatitis potential.

In fact, you should think twice in picking up those gloves if you are sensitised to chemicals. Even if you are not-sensitised, you should consider the availability of “suits me better” options that can reduce your risk of hypersensitivity.

As such, it will always be a good idea to look out for the labeling claims and warning statements of products at all time. At least you will be assured of concerns that you may have.

Warning statements are definitely not to be rejected negatively, instead they should be valued as LIFE SAVING statements!