ISO 15223-1:2007: Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements (International level). This part of ISO 15223 identifies requirements for the development and use of symbols that may be used to convey information on the safe and effective use of medical devices.

This part of ISO 3864 establishes the safety identification colors and design principles for safety signs to be used in workplaces and in public areas for the purpose of accident prevention, fire protection, health hazard information and emergency evacuation.

This European Norm (EN) has been prepared to describe the legislative regulations within the European Union (EU) for the use of symbols in medical device labelling, thereby reducing the need for multiple translations of words into national languages.

EU DIRECTIVE 98/79EC: In-vitro Diagnostic Medical Device Directive of the European Community (EC), published in 1998. This Directive recognizes the option of using harmonized symbols as a substitute for the different languages used in the EU: “Any symbol and identification colour used must conform to the harmonised standards. In areas for which no standards exist, the symbols and colour used must be described in the documentation supplied with the device.”

FDA 2004, 21 CFR 809.10 and 21 CFR parts 610 and 660: This document of the United States of America Food and Drug Administration provides Guidance on the use of selected symbols in place of text to convey some of the information required for in vitro diagnostic devices (IVDs) intended for professional use.

FDA recognizes 25 symbols for IVD devices for professional use from the following two international consensus standards: ISO 15223 and EN 980. FDA recommends that a glossary of terms accompany each IVD to define all of the symbols used on that device’s labels and/or labelling. This glossary may also contain other symbols identified by FDA in its recognition of ISO 15223 and EN 980.

Globally Harmonized System of Classification and Labeling of Chemicals (GHS): GHS is an internationally agreed upon system set to replace the various different classification and labeling standards used in different countries. It is a common and consistent approach to defining and classifying hazards, and communicating hazard information on labels and safety data sheets (SDS).