



Important Information Regarding Enteral Connectors and Comments ISO/FDIS 80369-3.doc

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IMPORTANT INFORMATION REGARDING ENTERAL (ENFit) CONNECTORS

The CSA Z298 Task Group for Small Bore Connectors and the Canadian Mirror Committee to ISO/TC 210 ("Canada") has identified serious deficiencies regarding draft standard ISO/FDIS 80369-3 *Small-bore connectors for liquids and gases in healthcare applications -- Part 3: Connectors for enteral applications*. Due to these deficiencies, "Canada" voted not to support this draft standard and provided technical reasons for this non-support. The attached is what was provided by "Canada", to ISO, describing those deficiencies.

While ISO 80369-3 has been published, "Canada" still does not support this standard. The comments from "Canada" have not been addressed. Nor have the comments provided by other countries (Member Bodies) been addressed.

In light of identified deficiencies associated with connectors designed to meet ISO 80369-3, "Canada" cannot recommend the use of these connectors.

"Canada" has been commended by various groups for its openness and transparency during this vetting process. "Canada" has listened to and considered comments from all sources, prior to making a well informed decision **NOT** to support this standard.

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Chair,

Z289 and SMC/ISO/TC 210