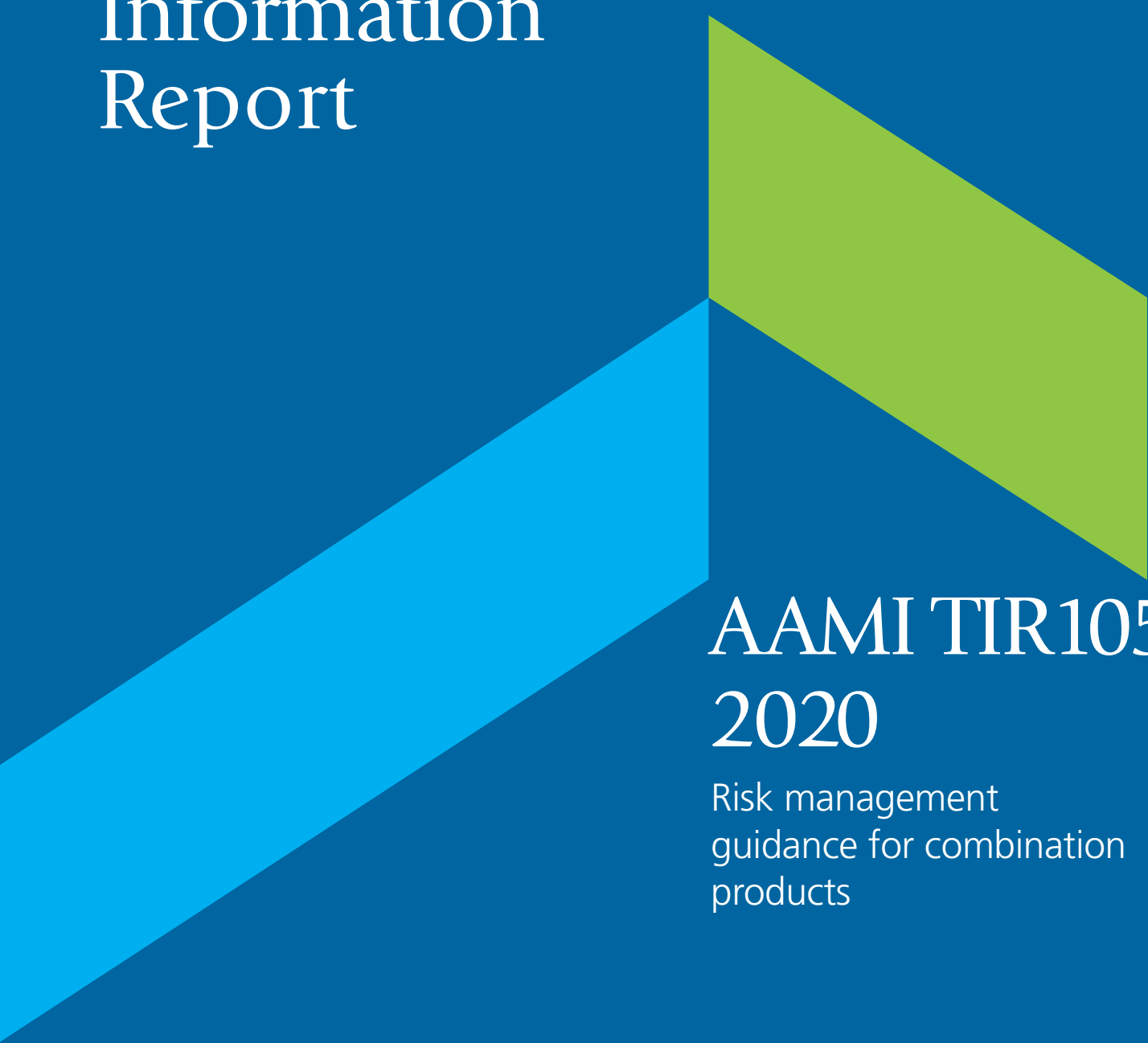


Technical Information Report



AAMI TIR105: 2020

Risk management
guidance for combination
products

Risk management guidance for combination products

Approved 10 September 2020 by
AAMI

Abstract: This technical information report provides recommendations and processes to assist manufacturers of combination products in identifying hazards associated with the combination product, assessing associated risks, selecting options for controlling these risks, and monitoring the effectiveness of the implemented controls.

Keywords: combination products, risk management

AAMI Technical Information Report

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Committee representation

Association for the Advancement of Medical Instrumentation

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This technical information report (TIR) was developed by the AAMI Combination Products Committee. Committee approval of the TIR does not necessarily imply that all committee members voted for its approval.

At the time this document was published, the **AAMI Combination Products Committee** had the following members:

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