(10)

# SYNOPSIS

Doc: **MHD 14 (14236) IS/IEC 62366-1:2015 Medical devices – Part 1: Application of usability engineering to medical devices**

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**a) Scope:**

This document specifies a process for a manufacturer to analyse, specify, develop and evaluate the usability of a medical device as it relates to safety. This usability engineering (human factors engineering) process permits the manufacturer to assess and mitigate risks associated with correct use and use errors, i.e., normal use. It can be used to identify but does not assess or mitigate risks associated with abnormal use.

**b) Salient features of content:**

This document identifies and describes terms and definitions, principles and Annex A, B, C and D.

**c) Type/grades/classes, if any covered in the standard**: Nil

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