(7)

SYNOPSIS

Doc: **MHD 14 (14237) IS/IEC/TR 62366-2:2016 Medical devices – Part 2: Guidance on the application of usability engineering to medical devices**

a) Scope:

This part of document which is a Technical Report, contains background information and provides guidance that addresses specific areas that experience suggests can be helpful for those implementing a usability engineering (human factors engineering) process both as defined in IS/IEC 62366-1:2015 and as supporting goals other than safety. This technical report is not intended to be used for regulatory purposes. It contains no requirements and only provides guidance and tutorial information.

b) Salient features of content:

This document identifies and describes terms and definitions, Mapping between the requirements of IEC 62366-1 and the guidance of IEC TR 62366-2, Background and justification of the usability engineering program, overview of the usability engineering process, Prepare the use specification, identify user interface characteristics related to safety and potential use errors, identify known or foreseeable Hazards and Hazardous situations, Establish user interface specification, Design and implement the user interface and training, Perform formative evaluations, Perform summative evaluation, Document the usability engineering project, post-production review and analysis.

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

20/10/19