(4)

SYNOPSIS

Doc: MHD 14 (14239) IS/ISO/TR 80002-2:2017 Medical device software — Part 2: Validation of software for medical device quality systems

a) Scope:

This document applies to any software used in device design, testing, component acceptance, manufacturing, labelling, packaging, distribution and complaint handling or to automate any other aspect of a medical device quality system as described in IS/ISO 13485.

This document applies to

— software used in the quality management system,

— software used in production and service provision, and

— software used for the monitoring and measurement of requirements.

It does not apply to

— software used as a component, part or accessory of a medical device, or

— software that is itself a medical device.

b) Salient features of content:

This document identifies and describes terms and definitions, Software validation discussion, Software validation and critical thinking, documentation, prerequisite processes and Annex A, B, C.

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

20/10/19