

SYNOPSIS

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Doc: **MHD 14 (14231) IS/ISO 15198:2004 Clinical laboratory medicine — In vitro diagnostic medical devices — Validation of user quality control procedures by the manufacturer** ✓

a) Scope:

This Standard describes a process for manufacturers of in vitro diagnostic medical devices to validate quality control procedures they recommend to their users. These quality control procedures are intended to provide users with assurance that device performance is consistent with its intended use and the manufacturers' claims. This Standard applies to all in vitro diagnostic medical devices

b) Salient features of content:

This document identifies and describes terms and conditions, Quality control procedures, Validation of quality control procedures and recommendations to users

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

Also mm
22/10/19