IEC TR 80002 2

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ISO/TR 80002-2:2017 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 ISO 13485. - software used for the monitoring and measurement of requirements.

ISO/TR 80002-2:2017 - Medical device software -- Part 2

IEC/TR 80002-1:2009(E) is aimed at risk management practitioners who need to perform risk management when software is included in the medical device/system, and at software engineers who need to understand how to fulfil the requirements for risk management addressed in ISO 14971.

IEC/TR 80002-1:2009 - Medical device software -- Part 1

IEC TR 80002-3 Edition 1.0 2014-06 INTERNATIONAL STANDARD Medical device software – Part 3: Process reference model of medical device software life cycle processes (IEC 62304) INTERNATIONAL ELECTROTECHNICAL COMMISSION U ICS 11.040.01 PRICE CODE ISBN 978-2-8322-1616-3 Warning!

Edition 1.0 2014-06 INTERNATIONAL STANDARD

IEC/TR 80002-1 Edition 1.0 2009-09 TECHNICAL REPORT Medical device software – Part 1: Guidance on the application of ISO 14971 to medical device software Edition 1.0 2014-06 INTERNATIONAL STANDARD

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ISO/TR 80002-2:2017(E) Foreword. ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees.

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ISO/TR 80002-2:2017(E) Figure 1 — Life-cycle controls. When considering using software in a process, one should identify whether the proposed software is. used as part of a medical device quality system process through an investigation of its intended use.

Provläsningsexemplar / Preview TECHNICAL ISO/TR REPORT 80002-2

IEC/TR 80002-1 and ISO 14971 Medical Devices Software Package The IEC/TR 80002-1 and ISO 14971 Medical Devices Software Package specifies the process of identifying, controling and monitoring risk and hazards associated with medical device software.

IEC/TR 80002-1 and ISO 14971 Medical Devices Software Package

ISO/TR 80002-2 is the future technical report on the validation of software used in regulated processed. The last version of this document, a Draft Technical Report (ISO/DTR 80002-2:2016), was released to the members of the standard committee for comments in May 2016.