

IEC/TR 80002-3:2014-06 (E)

Medical device software - Part 3: Process reference model of medical device software life cycle processes (IEC 62304)

Contents

	Page
FOREWORD.....	3
INTRODUCTION.....	5
0.1 Background.....	5
0.2 Organization of this technical report.....	5
1 Scope.....	6
2 Normative references.....	6
3 Terms and definitions.....	6
4 Medical device software life cycle processes.....	7
4.1 Software development process.....	7
4.1.1 Software development planning.....	7
4.1.2 Software requirements analysis.....	8
4.1.3 Software architectural design.....	8
4.1.4 Software detailed design.....	9
4.1.5 Software unit implementation and verification.....	9
4.1.6 Software integration and integration testing.....	10
4.1.7 Software system testing.....	10
4.1.8 Software release.....	11
4.2 Software maintenance.....	11
4.2.1 Purpose.....	11
4.2.2 Outcomes.....	11
4.3 Software risk management.....	12
4.3.1 Purpose.....	12
4.3.2 Outcomes.....	12
4.4 Software configuration management.....	13
4.4.1 Purpose.....	13
4.4.2 Outcomes.....	13
4.5 Software problem resolution.....	14
4.5.1 Purpose.....	14
4.5.2 Outcomes.....	14
Annex A (informative) Development of this technical report.....	16
Annex B (informative) Mapping between IEC 62304:2006 and ISO/IEC 12207:2008.....	18
Bibliography.....	28
Figure A.1 – Requirements in process elements of IEC 62304:2006 and ISO/IEC 12207:2008.....	16
Figure A.2 – Development of process outcomes for medical device software development PRM.....	17
Table A.1 – Direct process mappings between IEC 62304:2006 and ISO/IEC 12207:2008.....	17
Table B.1 – Mapping between process outcomes of the PRM and the requirements of IEC 62304:2006, including their safety classes, and the requirements of ISO/IEC 12207:2008 (1 of 9).....	19