

ISO/TR 80001-2-6:2014-12 (E)

Application of risk management for IT-networks incorporating medical devices - Part 2-6: Application guidance - Guidance for responsibility agreements

Contents	Page
Foreword	iv
Introduction	v
1 Scope	a
1.1 Purpose	a
1.2 Prerequisites	a
2 Normative references	a
3 Terms and definitions	a
4 Key aspects for RESPONSIBILITY AGREEMENTS	e
4.1 Reasons and rationale	e
4.2 Participants	e
4.3 Proposed types of RESPONSIBILITY AGREEMENTS	e
4.4 Communication control	e
4.4.1 Bilateral versus multilateral RESPONSIBILITY AGREEMENTS	e
4.4.2 Non-disclosure agreements	e
4.4.3 Update of information and documentation	f
4.5 Responsibility for establishing	f
4.6 Methods for determination and of responsibilities	f
4.7 Life cycle considerations	f
5 Elements of a RESPONSIBILITY AGREEMENT	g
Annex A (informative) RACI chart	k
Annex B (informative) Typical documents	12