

ISO 18562-1:2017-03 (E)

Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 1: Evaluation and testing within a risk management process

Contents		Page
Foreword		iv
Introduction		v
1	Scope	1
2	Normative references	2
3	Terms and definitions	2
4	General principles applying to biocompatibility evaluation of medical devices	6
4.1	General	6
4.2	Type tests	7
4.3	Biocompatibility hazard identification	8
4.4	Extent of risk assessment	8
4.5	Biocompatibility evaluation plan	9
4.6	Selection of tests	10
4.7	Subsequent evaluation	10
5	Contamination of breathing gas from gas pathways	11
5.1	* Duration of use	11
5.2	Particulate matter (pm) emissions	13
5.3	Volatile organic compound (voc) emissions	13
5.4	Leachable substances in condensate	13
6	Adjustment for different patient groups	13
6.1	General considerations	13
6.2	Adjustment for body weight	13
6.3	* Deriving a permitted concentration from a tolerable exposure	14
7	* Deriving allowable limits	14
7.1	General process	14
7.2	For medical devices intended for limited exposure use (24 h)	15
7.3	For medical devices intended for prolonged exposure use (>24 h but <30 d)	16
7.4	For medical devices intended for permanent contact (30 d)	16
8	Risk benefit analysis	16
9	Assess the biocompatibility of the medical device	17
Annex A (informative)	Rationale and guidance	18
Annex B (informative)	Reference to the essential principles	20
Annex C (informative)	Terminology--Alphabetized index of defined terms	21
Bibliography		23