ISO 18562-1:2024-03 (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* ... **11**
4.1 General ... 11
4.2 *Type tests* ... 14
4.3 *Biocompatibility hazard* identification ... 14
4.4 Extent of *risk assessment* ... 15
4.5 Biological evaluation plan ... 15
4.6 Selection of tests ... 17
4.7 Subsequent evaluation ... 18

5 Contamination of breathing gas from *gas pathways* ... **19**
5.1 Duration of use ... 19
5.2 *Particulate matter* (*PM*) emissions ... 19
5.3 *Volatile organic substance* emissions ... 20
5.4 *Leachables* in condensate ... 20

6 Adjustment of *exposure dose* and *inhalation dose* for different *patient* groups ... **20**
6.1 General considerations ... 20
6.2 Adjustment for different patient groups ... 20

7 Deriving *tolerable exposure* (*TE*) for *VOS* ... **21**
7.1 General *process* ... 21
7.2 For *medical devices* intended for limited exposure use (≤24 h) and prolonged exposure use (>24 h but <30 d) ... 22
7.3 For *medical devices* intended for long-term exposure (≥30 d) ... 23

8 Determining values for *leachables* in condensate ... **23**
8.1 General ... 23
8.2 Adjustments for different *patient* groups ... 24
8.3 *Exposure dose* estimate for condensate ... 24

9 *Risk control* ... **24**

10 *Benefit-risk analysis* ... **24**

11 Biological evaluation report ... **25**

Annex A (informative) **Rationale and guidance** ... **26**

Annex B (informative) **Reference to the IMDRF *essential principles* and labelling guidances** ... **28**

Annex C (informative) **Reference to the *essential principles*** ... **30**

Annex D (informative) **Terminology — Alphabetized index of defined terms** ... **31**

Bibliography ... **33**