

ISO 16021:2024-03 (E)

Absorbent incontinence products for urine and/or faeces - Basic principles for evaluation of single-use adult products from the perspective of users and caregivers

Contents	Page
Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Creating the evaluation protocol	2
4.1 Questionnaires.....	2
4.2 Selection of products.....	2
4.3 Selection of users.....	2
4.4 Sample size.....	3
4.5 Evaluation period.....	3
4.6 Product evaluation strategy.....	3
5 Data-gathering tools	3
5.1 Data requirements.....	3
5.2 Demographic data.....	4
5.3 Product evaluation data.....	4
5.3.1 Product evaluation questionnaire.....	4
5.3.2 Product diary.....	5
5.4 Product description data.....	5
5.5 Other documentation.....	5
6 User trial procedure	5
6.1 Pilot studies.....	5
6.2 Preparations.....	5
7 Data collection	6
7.1 Demographic data.....	6
7.2 Product performance data.....	6
7.2.1 Product evaluation questionnaire.....	6
7.2.2 Product change diary.....	6
7.3 User withdrawal.....	6
7.4 Product description data.....	7
7.5 Other documentation.....	7
8 Evaluation report	7
Bibliography	11