

ISO 17664-2:2021-02 (E)

Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices - Part 2: Non-critical medical devices

Contents

Page

Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	2
4 Risk analysis	4
5 Validation of the processes identified in the information provided by the medical device manufacturer	5
6 Information to be provided by the medical device manufacturer	5
6.1 General	5
6.2 Processing instructions	6
6.3 Limitations and restrictions on processing	7
6.4 Preparation before processing	7
6.5 Cleaning	7
6.5.1 General	7
6.5.2 Manual cleaning	7
6.5.3 Automated cleaning	8
6.6 Disinfection	8
6.6.1 General	8
6.6.2 Manual disinfection	8
6.6.3 Automated disinfection	9
6.7 Drying	9
6.8 Inspection and maintenance	9
6.9 Packaging	10
6.10 Storage	10
6.11 Transportation	10
7 Presentation of the information	10
Annex A (informative) Commonly utilized processing methods	11
Annex B (informative) Example processing instructions for non-critical reusable medical devices	15
Annex C (informative) Processing classification and grouping of medical devices	17
Annex D (informative) Additional guidance on information to be provided by the medical device manufacturer	19
Annex E (informative) Examples of medical devices and their relationship to this document	20
Bibliography	24