ISO 17664-1:2021 (E)

Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 1: Critical and semi-critical medical devices

Contents

Foreword

Introduction

1 Scope

2 Normative references

3 Terms and definitions

4 Validation of the processes identified in the information provided by the medical device manufacturer

5 Risk analysis

6 Information to be provided by the medical device manufacturer

- 6.1 General
- 6.2 Processing instructions
- 6.3 Limitations and restrictions on processing
- 6.4 Initial treatment at the point of use
- 6.5 Preparation before cleaning
- 6.6 Cleaning
- 6.6.1 General
- 6.6.2 Automated cleaning
- 6.6.3 Manual cleaning
- 6.7 Disinfection
- 6.7.1 General
- 6.7.2 Automated disinfection
- 6.7.3 Manual disinfection
- 6.8 Drying
- 6.9 Inspection and maintenance
- 6.10 Packaging
- 6.11 Sterilization
- 6.12 Storage
- 6.13 Transportation

7 Presentation of the information

Annex A (informative) Commonly utilized processing methods

Annex B (informative) Example of processing instructions for reusable medical devices

Annex C (informative) Classification of medical devices

- C.1 General
- C.2 Spaulding classification
- C.2.1 General
- C.2.2 Non-critical items
- C.2.3 Semi-critical items
- C.2.4 Critical items
- C.3 Medical device design groups for processing
- C.3.1 Key principles
- C.3.2 Design considerations

Annex D (informative) Additional guidance on information to be provided by the medical device manufacturer

D.1 Evaluation of appropriate processing methods (see Clause 6)
D.2 Generic information versus trade names (see 6.1.5)

Page count: 23