ISO 20072:2009-08 (E)

Aerosol drug delivery device design verification - Requirements and test methods

Contents

Page

Foreword iv

Introduction v

1 Scope 1

2 Normative references 1

3 Terms and definitions 2

4 Symbols and abbreviated terms 6

5 Requirements 7
5.1 General 7
5.2 Risk assessment requirements 8
5.3 Device functionality profile 8
5.4 System verification test 8
5.5 Uncertainty of measurements and conformance with specification 9
5.6 Test requirements 9

6 Test methods 11
6.1 General 11
6.2 Test procedures 12
6.3 Test conditions 16
6.4 Test evaluations 17

7 Test report 19

8 Information supplied by the manufacturer 19
8.1 General 19
8.2 Marking 19
8.3 Instructions for use 20

Annex A (informative) Rationale for requirements 22

Annex B (informative) Further guidance and clarification of the device functionality profile 24

Annex C (informative) Rationale for test methods 26

Annex D (informative) Two-sided tolerance limit factors (k) 29

Annex E (informative) Alternative acceptance criteria for the device functionality profile evaluation 35

Bibliography 42