

DIN EN ISO 20072:2011-01 (E)

Aerosol drug delivery device design verification - Requirements and test methods (ISO 20072:2009)

Contents		Page
Foreword		3
Introduction		4
1	Scope	6
2	Normative references	6
3	Terms and definitions	7
4	Symbols and abbreviated terms	11
5	Requirements	12
5.1	General	12
5.2	Risk assessment requirements	13
5.3	Device functionality profile	13
5.4	System verification test	13
5.5	Uncertainty of measurements and conformance with specification	14
5.6	Test requirements	14
6	Test methods	16
6.1	General	16
6.2	Test procedures	17
6.3	Test conditions	21
6.4	Test evaluations	22
7	Test report	24
8	Information supplied by the manufacturer	24
8.1	General	24
8.2	Marking	24
8.3	Instructions for use	25
Annex A (informative) Rationale for requirements		27
Annex B (informative) Further guidance and clarification of the device functionality profile		29
Annex C (informative) Rationale for test methods		31
Annex D (informative) Two-sided tolerance limit factors (k)		34
Annex E (informative) Alternative acceptance criteria for the device functionality profile evaluation		40
Bibliography		47
Annex ZA (informative) Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC on Medical Devices		49