

ISO 28620:2020-01 (E)

Medical devices - Non-electrically driven portable infusion devices

Contents		Page
	Foreword	iv
1	Scope	1
2	Normative references	1
3	Terms and definitions	2
4	General requirements	3
	4.1 Components.....	3
	4.2 Materials.....	4
	4.3 Design and characteristics.....	4
	4.3.1 General.....	4
	4.3.2 Fittings.....	4
	4.3.3 Filter.....	4
	4.3.4 Tubing.....	4
	4.3.5 Reservoir.....	4
	4.4 Sterility and non-pyrogenicity.....	4
5	Operating requirements	5
	5.1 Flow rate.....	5
	5.2 Bolus, if applicable.....	5
6	Test methods	5
	6.1 Test conditions.....	5
	6.1.1 General.....	5
	6.1.2 Apparatus and reagents.....	5
	6.1.3 Operating conditions.....	5
	6.2 Determination of the flow rate.....	6
	6.2.1 Principle.....	6
	6.2.2 Apparatus.....	6
	6.2.3 Procedure.....	6
	6.2.4 Expression of results.....	7
	6.3 Resistance to pressure.....	7
	6.4 Drop test method.....	7
	6.5 Water-tightness of the components of the device.....	8
	6.6 Resistance to traction of the entire device.....	8
	6.7 Bolus volume.....	8
	6.8 Refill time.....	8
	6.9 Test for efficiency of the fluid filter.....	9
	6.9.1 Preparation of the test fluid.....	9
	6.9.2 Procedure.....	9
	6.9.3 Expression of results.....	10
7	Information to be listed on packaging and/or product	10
8	Accompanying documents	11
	Bibliography	12