

ISO 7197:2024-07 (E)

Neurosurgical implants - Sterile, single-use hydrocephalus shunts

Contents		Page
Foreword		iv
Introduction		v
1	Scope	1
2	Normative references	1
3	Terms and definitions	1
4	General requirements for shunts	2
4.1	General	2
4.2	Radiopacity	2
4.3	Biocompatibility	2
4.4	Resistance to leakage	2
4.5	Control of the implanted shunt	3
4.6	Pressure-flow characteristics of the valve, the components and the pre-assembled shunt	3
4.7	Identification of shunts in vivo	3
4.8	Ability to withstand overpressure	3
4.9	Dynamic breaking strength	3
4.10	Behaviour under magnetic resonance imaging conditions	3
4.11	Bursting pressure	4
5	Specific requirements for components	4
5.1	Valves	4
5.1.1	Reflux performance of shunts connecting the ventricle to the blood system	4
5.1.2	Long-term stability	4
5.1.3	Influence of the changed posture of the patient on the valve performance	4
5.2	Resistance of tubing and components	5
6	Marking and labelling of shunts	5
7	Packaging	5
8	Information supplied by the manufacturer	5
8.1	General	5
8.2	Instructions for use	5
8.3	Implant card	6
Bibliography		7