

ISO 10451:2026-03 (E)

Dentistry - Contents of a technical file for dental implant systems

Contents		Page
Foreword		iv
Introduction		v
1	Scope	1
2	Normative references	1
3	Terms and definitions	3
4	Technical file content and requirements	3
4.1	General	3
4.2	Device description and specification	4
4.3	Risk analysis	5
4.4	Infection and microbial contamination	5
4.5	Manufacturing information	5
4.6	Verification and validation activities	6
4.7	Clinical evaluation and clinical investigation	7
4.8	Information supplied by the manufacturer	8
4.9	Post market surveillance	9
	Annex A (informative) List of identified hazards for dental implants	10
	Bibliography	12