

# ISO 10993-15:2019-11 (E)

## Biological evaluation of medical devices - Part 15: Identification and quantification of degradation products from metals and alloys

---

<b>Contents</b>		<b>Page</b>
Foreword .....		iv
Introduction .....		v
1	Scope .....	1
2	Normative references .....	1
3	Terms and definitions .....	2
4	Degradation test methods .....	3
4.1	General .....	3
4.2	Prerequisites .....	3
5	Reagent and sample preparation .....	4
5.1	Sample documentation .....	4
5.2	Test solution (electrolyte) .....	4
5.3	Preparation of test samples .....	4
5.3.1	Test samples .....	4
5.3.2	Sampling .....	4
5.3.3	Sample shape .....	4
5.3.4	Sample surface condition .....	5
6	Electrochemical tests .....	5
6.1	Apparatus .....	5
6.2	Sample preparation .....	5
6.3	Test conditions .....	5
6.4	Potentiodynamic measurements .....	6
6.5	Potentiostatic measurements .....	8
7	Immersion test .....	9
7.1	Apparatus .....	9
7.2	Sample preparation .....	9
7.3	Immersion test procedure .....	9
8	Analysis .....	10
9	Test report .....	10
Annex A (informative)	Electrolytes for the electrochemical tests .....	12
Annex B (informative)	Schematic diagram of the electrochemical measuring circuit .....	13
Annex C (informative)	Schematic drawing of an electrolytic cell .....	14
Bibliography .....		15