

DIN EN ISO 10993-15:2023-07 (E)

Biological evaluation of medical devices - Part 15: Identification and quantification of degradation products from metals and alloys (ISO 10993-15:2019)

Contents	Page
European foreword	3
Annex ZA (informative) Relationship between this European Standard the General Safety and Performance Requirements of Regulation (EU) 2017/745 aimed to be covered	4
Foreword	7
Introduction	8
1 Scope	9
2 Normative references	9
3 Terms and definitions	10
4 Degradation test methods	11
4.1 General.....	11
4.2 Prerequisites.....	11
5 Reagent and sample preparation	12
5.1 Sample documentation.....	12
5.2 Test solution (electrolyte).....	12
5.3 Preparation of test samples.....	12
5.3.1 Test samples.....	12
5.3.2 Sampling.....	12
5.3.3 Sample shape.....	12
5.3.4 Sample surface condition.....	13
6 Electrochemical tests	13
6.1 Apparatus.....	13
6.2 Sample preparation.....	13
6.3 Test conditions.....	13
6.4 Potentiodynamic measurements.....	14
6.5 Potentiostatic measurements.....	16
7 Immersion test	17
7.1 Apparatus.....	17
7.2 Sample preparation.....	17
7.3 Immersion test procedure.....	17
8 Analysis	18
9 Test report	18
Annex A (informative) Electrolytes for the electrochemical tests	20
Annex B (informative) Schematic diagram of the electrochemical measuring circuit	21
Annex C (informative) Schematic drawing of an electrolytic cell	22
Bibliography	23