

DIN EN ISO 10993-9:2022-03 (E)

Biological evaluation of medical devices - Part 9: Framework for identification and quantification of potential degradation products (ISO 10993-9:2019)

Contents		Page
European foreword		3
Annex ZA (informative) Relationship between this European Standard and the general health and safety requirements of Regulation (EU) 2017/745 on medical devices aimed to be covered		5
Foreword		7
Introduction		8
1	Scope	9
2	Normative references	9
3	Terms and definitions	9
4	Principles for design of degradation studies	10
4.1	General	10
4.2	Preliminary considerations	11
4.3	Study design	11
4.4	Characterization of degradation products from medical devices	12
5	Study report	12
Annex A (normative) Consideration of the need for degradation studies		14
Annex B (informative) Degradation study considerations		16
Bibliography		18