

DIN EN ISO 14630:2025-03 (E)

Non-active surgical implants - General requirements (ISO 14630:2024)

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	10
Introduction	12
1 Scope	13
2 Normative references	13
3 Terms and definitions	14
4 Intended performance	18
5 Design attributes	18
6 Selection of materials	19
7 Design evaluation	20
7.1 General.....	20
7.2 Pre-clinical evaluation.....	20
7.3 Clinical evaluation and clinical investigation.....	22
7.4 Post-market surveillance.....	23
8 Manufacture	23
9 Sterilization	23
9.1 Implants supplied sterile.....	23
9.2 Implants supplied non-sterile.....	24
9.3 Re-sterilizable implants.....	24
9.4 Sterilization residuals.....	24
10 Packaging	24
10.1 Protection from damage in transport, storage and handling.....	24
10.2 Maintenance of sterility in transport, storage and handling.....	25
10.3 Use by date.....	25
11 Information supplied by the manufacturer	25
11.1 General.....	25
11.2 Marking on implants.....	26
11.3 Label.....	26
11.4 Instructions for use.....	28
11.5 Patient record label(s).....	29
11.6 Implant card.....	30
11.7 Implants for special purposes.....	30
Bibliography	31