DIN EN ISO 14644-4:2023-04 (E)

Cleanroo ms and associated controlled environments - Part 4: Design, construction and start-up (ISO 14644-4:2022)

Contents

Page

European foreword ... **3**

Foreword ... **4**

Introduction ... **5**

1 Scope ... **6**

2 Normative references ... **6**

3 Terms and definitions ... **6**
3.1 General ... 7
3.2 Installation ... 10

4 Abbreviated terms ... 10

5 General ... **11**

6 Requirements ... **12**
6.1 Cleanroom requirements ... **12**
6.2 Other requirements ... 14
6.3 Documentation ... 14

7 Design ... **14**
7.1 General ... 14
7.2 Conceptual design ... 15
7.3 Basic design ... 15
7.4 Detailed design ... 16
7.5 Change management ... 16

8 Construction ... **17**
8.1 General ... 17
8.2 Construction plan ... 17
8.2.1 General ... 17
8.2.2 Schedule ... 17
8.2.3 Quality plan ... 17
8.2.4 Clean build protocol ... 17
8.3 Construction verification ... 18
8.4 Documentation ... 18

9 Start-up ... **18**
9.1 General ... 18
9.2 Commissioning ... 19
9.2.1 General ... 19
9.2.2 Setting to work ... 19
9.2.3 Functional and performance verifications ... 19
9.3 Training ... 19
9.4 Handover ... 19
9.5 Documentation ... 19
9.5.1 Commissioning documentation ... 19
9.5.2 Performance-monitoring instructions ... 20
9.5.3 Maintenance instructions ... 20
9.5.4 Maintenance record ... 20
9.5.5 Record of training ... 20

Annex A (informative) **Guidance on requirements** **21**
Annex B (informative) **Guidance on design** **29**
Annex C (informative) **Guidance on construction** **50**
Annex D (informative) **Guidance on start-up** **56**
Bibliography **61**