DIN EN ISO 23371:2022-08 (E)

Anaesthetic and respiratory equipment - Cuff pressure indication, control and regulation devices (ISO 23371:2022)

Contents

Page

European foreword ... **3**

Foreword ... **4**

Introduction ... **5**

1 Scope ... **6**

2 Normative references ... **6**

3 Terms and definitions ... **6**

4 General requirements ... **7**
4.1 General ... 7
4.2 Alternative test methods ... 7

5 Materials ... **8**

6 Design requirements ... **8**
6.1 General ... 8
6.2 Metrological requirements ... 8
6.3 Connectors ... 9
6.4 *Integrated cuff pressure indicators* ... 9
6.5 Mechanical strength ... 10

7 Requirements for Cuff pressure indication, control and regulation devices supplied sterile ... **10**

8 Packaging ... **11**

9 Information supplied by the manufacturer ... **11**
9.1 General ... 11
9.2 Marking ... 11
9.2.1 General ... 11
9.2.2 Markings ... 11
9.3 Instructions for use ... 11

Annex A (Informative) **Rationale** ... **13**

Bibliography ... **14**