

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 <i>Integrated cuff pressure indicators</i> | 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 |