



SLOVENSKI STANDARD
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Tlačni regulatorji za medicinske pline - 3. del: Tlačni regulatorji v sklopu cilindričnih ventilov jeklenk (ISO/DIS 10524-3:2025)

Pressure regulators for use with medical gases - Part 3: Pressure regulators integrated with cylinder valves (VIPRs) (ISO/DIS 10524-3:2025)

Druckminderer zur Verwendung mit medizinischen Gasen - Teil 3: Druckminderer in Flaschenventilen (ISO/DIS 10524-3:2025)

Détendeurs pour l'utilisation avec les gaz médicaux - Partie 3: Détendeurs intégrés dans les robinets des bouteilles à gaz (VIPR) (ISO/DIS 10524-3:2025)

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Pressure regulators for use with medical gases —

Part 3: Pressure regulators integrated with cylinder valves (VIPRs)

Détendeurs pour l'utilisation avec les gaz médicaux —

Partie 3: Détendeurs intégrés dans les robinets des bouteilles à gaz (VIPR)

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171 Foreword

172 ISO (the International Organization for Standardization) is a worldwide federation of national
173 standards bodies (ISO member bodies). The work of preparing International Standards is
174 normally carried out through ISO technical committees. Each member body interested in a subject
175 for which a technical committee has been established has the right to be represented on that
176 committee. International organizations, governmental and non-governmental, in liaison with ISO,
177 also take part in the work. ISO collaborates closely with the International Electrotechnical
178 Commission (IEC) on all matters of electrotechnical standardization.

179 The procedures used to develop this document and those intended for its further maintenance
180 are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria
181 needed for the different types of ISO documents should be noted. This document was drafted in
182 accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

183 ISO draws attention to the possibility that the implementation of this document may involve the
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193 expressions related to conformity assessment, as well as information about ISO's adherence to
194 the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see
195 www.iso.org/iso/foreword.html.

196 This document was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory*
197 *equipment*, Subcommittee SC 6, *Medical gas supply systems*.

198 This third edition cancels and replaces the second edition (ISO 10524-3:2019), which has been
199 technically revised.

200 The main changes are as follows:

- 201 — reorganisation of the structure of the document
- 202 — Alignment on the requirements of ISO 10297:2024, Gas cylinders — Cylinder valves —
203 Specification and type testing
- 204 — Alignment of terms with ISO 10297 and ISO 15002
- 205 — New requirement regarding the potential contamination of the gas pathway
- 206 — New requirement regarding cleaning and disinfection
- 207 — Definition of three temperature ranges
- 208 — References to colour coding have been removed
- 209 — Specific requirements for *VIPRs* intended to supply air or nitrogen for driving surgical
210 tools moved to an normative annex
- 211 — New informative annex on qualification of a *VIPR* for use in an air / road ambulance
- 212 — New informative annex on the promoted ignition test (ASTM G175-24)

213 A list of all parts in the ISO 10524 series can be found on the ISO website.

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214 Any feedback or questions on this document should be directed to the user's national standards
215 body. A complete listing of these bodies can be found at www.iso.org/members.html.
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217 Introduction

218 Medicinal gases can be supplied in cylinder fitted with *Valves with Integrated Pressure*
 219 *regulators (VIPRs)*. High pressure cylinders fitted with a *VIPR* offers the patient and the
 220 healthcare professional with a safe and convenient package to administer the gas without
 221 having to connect a separate *pressure regulator*.

222 The *VIPR* is normally fitted with an *integral flow control device* incorporating a *flow outlet* to
 223 allow the prescribed flow to be administered and can be fitted with a *pressure outlet*, using a
 224 *gas-specific* terminal outlet, as used for medical gas pipeline systems.

225 In order for the medicinal gas to be administered safely to the patient, the design
 226 specifications and characteristics of the *VIPR* need to be controlled to ensure that the flows
 227 and pressures are compatible with any medical devices used with the cylinder package.

228 This standard describes basic requirements for the *VIPRs* used with medical gas cylinder
 229 packages including:

- 230 • Suitable materials of construction, compatible with the medicinal gases
- 231 • Safe design principles, including requirements for:
 - 232 • usability and handling;
 - 233 • mechanical strength,
 - 234 • operational characteristics (flowrates and pressures);
 - 235 • pressure relief systems;
 - 236 • product integrity (leakage);
 - 237 • resistance to ignitions.
- 238 • Gas-specificity
- 239 • Cleanliness
- 240 • Marking
- 241 • Information for safe usage by the medical gas supplier and the end user

242 The standard describes the approved tests for the type testing of the *VIPR* and the acceptance
 243 limits for the tests.

244 *VIPRs* also act as the “closure” of gas cylinders, and both gas cylinders and closures are subjected
 245 to transport regulations. ISO 10297, *Gas cylinders — Cylinder valves — Specification and type*
 246 *testing* standard, developed by ISO/TC 58/SC 2 is the ISO cylinder valve (closure) standard
 247 referenced in these regulations. ISO 10297 includes industrial and medical *VIPRs* within its scope
 248 and was recently revised,

249 Medical *VIPRs* are classified as medical devices and have to comply with the medical device
 250 regulations. As a medical device standard, ISO 10524-3 is intended to demonstrate conformity
 251 with the safety and performance requirements as defined in medical devices regulations and
 252 recognised guidelines. As, ISO 10524-3 strives to comprehensively cover all aspects related to
 253 safety and performances of the medical *VIPR*, it makes having a general reference to ISO 10297
 254 impractical.

255 In order to reconcile these regulatory constraints and minimize burden on manufacturers, the
 256 chosen approach is to replicate the applicable “medical” requirements common to both standards
 257 within ISO 10524-3, along with a note indicating alignment with ISO 10297:2024. Some of the
 258 requirements of ISO 10297 are not relevant for medical devices and have not been duplicated.

259 However, for those tests methods that are relevant, direct reference to ISO 10297:2024 is made,
 260 so avoiding duplication.

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261 1 Scope

262 This document specifies design, type testing, and marking requirements for cylinder valves with
263 integrated *pressure regulators* [as defined in 3.26 and referred to hereafter as *valves with*
264 *integrated pressure regulators (VIPRs)*].

265 Medical *VIPRs* are designed to be mounted on medical gas cylinders, allowing them to be filled
266 with medical gases for subsequent use as a supply source for other medical devices, such as
267 emergency ventilators, or for the direct administration of medical gases to a patient via an
268 *integral flow control device*, when fitted.

269 Examples of medical gases include oxygen, medical air and oxygen/nitrous oxide mixtures.

270 Intended use of *VIPRs* may also encompass the supply of air or nitrogen for driving surgical tools.

271 NOTE See annex B for their specific requirements

272 This document applies to *VIPRs* mounted on refillable cylinders with a *working pressure* up to
273 30 000 kPa (300 bar) intended to be filled in cylinder filling facilities or on self-filling systems as
274 used in homecare applications.

275 *VIPRs* covered by this document are pressure pre-set and provided with a *pressure outlet* and/or
276 pre-set *flow outlet(s)*.

277 *VIPRs* used for self-fill systems used in homecare are not covered by this standard, but it can be
278 used as a guide.

279 NOTE The conditions of use for these *VIPRs* vary significantly, particularly in terms of filling frequency
280 and usage, which can occur daily throughout their lifetime.

281 2 Normative references

282 The following documents are referred to in the text in such a way that some or all of their content
283 constitutes requirements of this document. For dated references, only the edition cited applies.
284 For undated references, the latest edition of the referenced document (including any
285 amendments) applies.

286 ISO 5145, *Gas cylinders — Cylinder valve outlets for gases and gas mixtures — Selection and*
287 *dimensioning*

288 ISO 9170-1, *Terminal units for medical gas pipeline systems — Part 1: Terminal units for use with*
289 *compressed medical gases and vacuum*

290 ISO 10297:2024, *Gas cylinders — Cylinder valves — Specification and type testing*

291 ISO 11114-6, *Gas cylinders — Compatibility of cylinder and valve materials with gas contents —*
292 *Part 6: Oxygen pressure surge testing*

293 ISO 11117, *Gas cylinders — Valve protection caps and valve guards — Design, construction and*
294 *tests*

295 ISO 11363-1, *Gas cylinders — 17E and 25E taper threads for connection of valves to gas cylinders*
296 *— Part 1: Specifications*

297 ISO 13341, *Gas cylinders — Fitting of valves to gas cylinders*

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- 298 ISO 14971, *Medical devices — Application of risk management to medical devices*
- 299 ISO 15001, *Anaesthetic and respiratory equipment — Compatibility with oxygen*
- 300 ISO 15245-1, *Gas cylinders — Parallel threads for connection of valves to gas cylinders — Part 1:*
301 *Specification*
- 302 ISO 15996, *Gas cylinders — Residual pressure valves — Specification and type testing of cylinder*
303 *valves incorporating residual pressure devices*
- 304 ISO 17256, *Anaesthetic and respiratory equipment — Respiratory therapy tubing and connectors*
- 305 ISO 20417, *Medical devices — Information to be supplied by the manufacturer*
- 306 EN 837-1, *Pressure gauges — Part 1: Bourdon tube pressure gauges — Dimensions, metrology,*
307 *requirements and testing*

308 **3 Terms and definitions**

309 For the purposes of this document, the following terms and definitions apply.

310 ISO and IEC maintain terminological databases for use in standardization at the following
311 addresses:

312 — ISO Online browsing platform: available at <https://www.iso.org/obp>

313 — IEC Electropedia: available at <http://www.electropedia.org/>

314 **3.1**

315 **accuracy of flow**

316 difference between the indicated flow and the measured flow

317 Note 1 to entry: Expressed as a percentage.

318 **3.2**

319 **content indicator**

320 device that indicates the cylinder content

321 Note 1 to entry: The content can be expressed either in percentage of content, volume of gas or cylinder
322 pressure.

323 **3.3**

324 **filling adaptor**

325 means of connecting the *VIPR filling port* to the filling system allowing a cylinder fitted with a
326 *VIPR* to be filled or vented

327 Note 1 to entry: This is not part of the *VIPR*.

328 Note 2 to entry: It may also be referred to as a filling tool.

329 **3.4**

330 **filling port**

331 connector on the *VIPR* through which the cylinder is filled

332 **3.5**

333 **filling port non-return valve**

334 valve which remains closed in normal use thus preventing the flow out of the *VIPR's filling port*

335 until opened by insertion of an appropriate means and which then permits flow in either

336 direction