

تقديم

الهيئة العامة للغذاء والدواء جهة مستقلة الغرض الأساسي لها هو القيام بتنظيم ومراقبة الغذاء والدواء والأجهزة والمنتجات الطبية والتشخيصية، ومن مهامها وضع اللوائح الفنية والمواصفات في مجالات الغذاء والدواء والأجهزة والمنتجات الطبية سواء كانت مستوردة أو مصنعة محلياً بواسطة لجان فنية متخصصة، وقد قام قطاع الأجهزة والمنتجات الطبية بالهيئة بتبني المواصفة الخليجية رقم (GSO 2016: ISO 7396-1 (E) 2016: ISO 7396-1) " أنظمة خط أنبوب الغاز الطبي - الجزء 1: أنظمة الضغط والشفط لخط أنبوب الغازات الطبية " وذلك بلغتها الأصلية. وقد اعتمدت هذه المواصفة كمواصفة سعودية متبناة بالمطابقة بلغتها الأصلية وذلك في اجتماع مجلس الإدارة رقم () والذي عقد بتاريخ (14.././.. هـ) الموافق (20.././.. م).

Foreword

Saudi Food and Drug Authority (SFDA) is an independent organization with purpose of regulating and monitoring of foods, drugs and medical devices. One of SFDA functions is to issue national Standards /Technical Regulation in the fields of foods, drugs and medical devices, whether imported or manufactured locally, through specialized technical committees (TCs).SFDA medical devices sector has adopted Standard No. (ISO 7396-1:2016 (E) ISO 7396-1:2016) "Medical gas pipeline systems — Part 1: Pipeline systems for compressed medical gases and vacuums "GCC Standardization Organization" in its original language. This standard is adopted identically in its original language and has been approved as national standard by SFDA board of directors in its meeting No () Held on (/// AH) , agreed with (// G).

Medical gas pipeline systems —
Part 1:
Pipeline systems for compressed
medical gases and vacuum

Systèmes de distribution de gaz médicaux —

Partie 1: Systèmes de distribution de gaz médicaux comprimés et de vide

Scope

This part of ISO 7396 specifies requirements for design, installation, function, performance, testing, commissioning and documentation of pipeline systems used in healthcare facilities for the following:

- oxygen;
- nitrous oxide;
- medical air;
- carbon dioxide;
- oxygen/nitrous oxide mixtures (see Note 1);
- helium/oxygen mixtures;
- (*) oxygen 93;
- gases and gas mixtures classified as medical device, gases delivered to medical devices or intended for medical purposes or gases and gas mixtures for medicinal use not specified above;
- air for driving surgical tools;
- nitrogen for driving surgical tools;
- vacuum.

NOTE 1 Regional or national regulations may prohibit the distribution of oxygen/nitrous oxide mixtures in medical gas pipeline systems.

NOTE 2 Anaesthetic gas scavenging disposal systems are covered in ISO 7396-2.

This part of ISO 7396 includes requirements for supply systems, pipeline distribution systems, control systems, monitoring and alarm systems and non-interchangeability between components of different gas/vacuum systems.

This part of ISO 7396 specifies safety requirements for pipeline systems used in healthcare facilities, both public and private. It applies to all facilities providing healthcare services regardless of type, size, location or range of services, including, but not limited to:

- a) acute care healthcare facilities;
- b) internal patient continuing care healthcare facilities;
- c) long-term care facilities;
- d) community-based providers;
- e) ambulatory and external patient care clinics (e.g. day surgery, endoscopy clinics and doctors' offices).

NOTE 3 This part of ISO 7396 may also be used as reference for pipeline systems for medical gases and vacuum intended to be installed in places other than healthcare facilities.

This part of ISO 7396 applies to the following different types of oxygen supply systems:

- supply systems in which all sources of supply deliver oxygen; in this case the concentration of the oxygen will be greater than 99%;
- supply systems in which all sources of supply deliver oxygen 93; in this case the concentration of the oxygen may vary between 90% and 96%;

NOTE 4 A mixture of oxygen 93 and oxygen may be delivered by a medical gas supply system. In this case the

concentration of the gas can vary between 90% and >99%.

This part of ISO 7396 also applies to:

- extensions of existing pipeline distribution systems;
- modifications of existing pipeline distribution systems;
- modifications or replacement of supply systems or sources of supply.

Oxygen concentrators for domiciliary use are excluded from the scope of this part of ISO 7396.

NOTE 5 Requirements for oxygen concentrators for domiciliary use are specified in ISO 80601 -2-69.

(*) EN 14931 defines additional requirements for hyperbaric application, in particular for flows and pressures of

compressed air required to pressurize the hyperbaric chamber and to drive other connected services.

Also included are requirements for oxygen and other treatment gases administered to patients.

This part of ISO 7396 does not apply to vacuum systems intended to be used in dentistry.

This part of ISO 7396 does not apply to filling systems for transportable cylinders and transportable

cylinder bundle systems.

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