

International Organization for Standardization Organisation internationale de normalisation Международная организация по стандартизации

Ch. de Blandonnet 8 | CP 401, 1214 Vernier | Geneva, Switzerland | T: +41 22 749 01 11 | central@iso.org | www.iso.org

Your ref. Our ref.

COPOLCO N531

TO THE MEMBERS OF COPOLCO

Date 2020-04-21

COVID-19 response by ISO, its members and partners

Dear Sir or Madam,

We would like to share some information about initiatives to counter the COVID-19 pandemic, which we invite you to share with your stakeholders.

ISO's leadership recently decided to make certain International Standards and their national adoptions (eg on security and resilience, medical devices and protective equipment) available without charge in read-only format through the ISO member channel. See the enclosed letter for more details.

Some COPOLCO member representatives are leading national initiatives to address new challenges arising from the pandemic. AFNOR has released <u>a national reference document on protective face masks</u>, and BSI has developed a web page to <u>share knowledge of good practices and selected standards</u>.

A dedicated area of ISO's website features <u>members' actions to deal with the COVID-19 crisis</u>. If your NSB has an experience to share and has not already done so, please contact us at <u>copolco@iso.org</u>.

ISO is part of the international community's large-scale effort; on 17 April ISO collaborated with UNIDO and several other international organizations to run a webinar on Quality, Testing and Standards in the Fight against COVID-19. Consumers International has set up a COVID-19 portal with a joint statement calling for concerted action to protect consumers. The portal also shares relevant work of many international organizations and agencies, including an article from the UNCTAD Competition and Consumer Policies branch warning against unfair business practices and criminal activities.

You may already know that all ISO technical and governance meetings up until 31 July 2020 are to be held virtually or postponed, pending further notice. The ISO Technical Management Board has decided to take <u>special measures for technical work</u>, as outlined in the *Standards* area of *ISO Connect*.

Please transmit this information to your network. In the meantime, stay safe and well.

Yours faithfully,

Dana Kissinger-Matray Secretary of ISO/COPOLCO

Dans Minnyer-Matry

Ch. de Blandonnet 8 | CP 401, 1214 Vernier | Geneva, Switzerland | T: +41 22 749 01 11 | central@iso.org | www.iso.org

Sergio Mujica Secretary-General TO ISO MEMBER BODIES AND CORRESPONDENT MEMBERS

Free availability of standards: Update and expansion to list

2020-04-02

UPDATE: AVAILABILITY OF ISO STANDARDS AND THEIR NATIONAL ADOPTIONS IN RESPONSE TO THE COVID-19 OUTBREAK

Dear Members,

Further to my communication dated 25 March 2020, after further consultation with the ISO President and the Chair of ISO's Commercial Policy Advisory Group (CPAG), it has been decided to expand the list of ISO Standards ("licensed materials") and their national adoptions that members can make freely accessible online in **read-only format**.

The list (see Annex), which has been compiled in to order to support global efforts to deal with the COVID-19 crisis, now includes a series of standards related to respirators and essential medical devices.

This action has been coordinated with the International Electrotechnical Commission (IEC), who are making complementary standards freely available at https://go.iec.ch/covid19faq.

Conditions for making standards freely available online in read-only format remain as indicated in my previous communication and are applicable to all standards listed. This same communication also outlines the conditions for ISO members to provide free of charge, on a case-by-case basis, individual copies of these standards (in PDF or paper versions).

The permission to make the content of ISO Standards and their national adoptions freely accessible **only applies to the standards listed in the** Annex **and is strictly limited to ISO members**. Commercial distributors receiving such requests must redirect them to the ISO member in the country where the request originated.

It has been decided that ISO/CS will be making the standards outlined in the annex freely available in **read-only format on the ISO Online Browsing Platform (OBP)**, with direct links available via www.iso.org/covid19. Members may make links to these standards if they wish.

The possibility to provide free access to these standards, as outlined, remains in effect until further advised.

I would like to take this opportunity to thank all members for their efforts during this unique time. We have developed a dedicated page on iso.org to highlight the resources made available by members to support the fight against COVID-19 (see www.iso.org/covid19-members). Should you wish to have you own pages listed there please let us know by sending an email to marketing@iso.org.

Best regards, Sergio Mujica

500

Free availability of standards: Update and expansion to list Page 2

Annex

LIST OF ISO STANDARDS AND THEIR NATIONAL ADOPTIONS THAT CAN BE MADE FREELY AVAILABLE¹ IN RESPONSE TO THE COVID-19 OUTBREAK

www.iso.org/covid19

ISO Standards identified in communication to members 2020-03-25

- <u>ISO 374-5:2016</u>, Protective gloves against dangerous chemicals and micro-organisms -Part 5: Terminology and performance requirements for micro-organisms risks
- ISO 10993-1:2018, Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process
- ISO 13688:2013, Protective clothing General requirements
- ISO 22301:2019, Security and resilience Business continuity management systems Requirements
- ISO 22395:2018, Security and resilience Community resilience Guidelines for supporting vulnerable persons in an emergency
- <u>ISO 22320:2018</u>, Security and resilience Emergency management Guidelines for incident management
- ISO 22316:2017, Security and resilience Organizational resilience Principles and attributes
- ISO 31000:2018, Risk management Guidelines

List of standards related to respirators and essential medical devices

- ISO 10651-3:1997, Lung ventilators for medical use Part 3: Particular requirements for emergency and transport ventilators
- ISO 10651-4:2002, Lung ventilators Part 4: Particular requirements for operatorpowered resuscitators
- ISO 10651-5:2006, Lung ventilators for medical use Particular requirements for basic safety and essential performance Part 5: Gas-powered emergency resuscitators
- <u>ISO 13485:2016</u>, Medical devices Quality management systems Requirements for regulatory purposes
- ISO 17510:2015, Medical devices Sleep apnoea breathing therapy Masks and application accessories
- ISO 18082:2014, Anaesthetic and respiratory equipment Dimensions of noninterchangeable screw-threaded (NIST) low-pressure connectors for medical gases [Including ISO 18082:2014/Amd.1:2017, <u>AMENDMENT 1</u>]
- ISO 18562-1:2017, Biocompatibility evaluation of breathing gas pathways in healthcare applications Part 1: Evaluation and testing within a risk management process
- ISO 18562-2:2017, Biocompatibility evaluation of breathing gas pathways in healthcare applications Part 2: Tests for emissions of particulate matter
- ISO 18562-3:2017, Biocompatibility evaluation of breathing gas pathways in healthcare applications Part 3: Tests for emissions of volatile organic compounds (VOCs)
- ISO 18562-4:2017, Biocompatibility evaluation of breathing gas pathways in healthcare applications Part 4: Tests for leachables in condensate
- ISO 19223:2019, Lung ventilators and related equipment Vocabulary and semantics
- ISO 20395:2019, Biotechnology Requirements for evaluating the performance of quantification methods for nucleic acid target sequences — qPCR and dPCR

*

¹ Availability is restricted to the conditions outlined in the letter to ISO members '2020-03-25, Free availability of standards'

Free availability of standards: Update and expansion to list Page 3

- <u>ISO 5356-1:2015</u>, Anaesthetic and respiratory equipment Conical connectors Part
 1: Cones and sockets
- ISO 80601-2-12:2020, Medical electrical equipment Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators
- ISO 80601-2-13:2011, Medical electrical equipment Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation [Including: ISO 80601-2-13:2011/Amd.1:2015, AMENDMENT 1] and ISO 80601-2-13:2011/Amd.2:2018, AMENDMENT 2]
- ISO 80601-2-70:2015, Medical electrical equipment Part 2-70: Particular requirements for basic safety and essential performance of sleep apnoea breathing therapy equipment
- ISO 80601-2-74:2017, Medical electrical equipment Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment
- <u>ISO 80601-2-79:2018</u>, Medical electrical equipment Part 2-79: Particular requirements for basic safety and essential performance of ventilatory support equipment for ventilatory impairment
- ISO 80601-2-80:2018, Medical electrical equipment Part 2-80: Particular requirements for basic safety and essential performance of ventilatory support equipment for ventilatory insufficiency
- <u>ISO/TS 16976-8:2013</u>, Respiratory protective devices Human factors Part 8: Ergonomic factors