International Standard

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Horology — Harmonized practices to demonstrate chemical regulatory compliance of wrist-watches

Horlogerie — Pratiques harmonisées permettant d'établir la conformité réglementaire chimique des montres-bracelets

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Foreword

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This document was prepared by Technical Committee ISO/TC 114, *Horology*.

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

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Introduction

Like many other commercial products, wrist-watches are subject to a range of evolving international trade regulations, with a focus on protecting the human health and the environment.

The field of wristwatch safety is not governed by a specific regulatory framework. Consequently, the compliance of wristwatches falls under various regulations. Due to the potential combination of distinctive features such as advanced technical functions, an extensive array of components, and a diverse assortment of materials having a direct and prolonged skin contact, wristwatches might be subject to regulatory mandates that may not adequately correspond to the actual health risks involved.

Therefore, this document aims to establish and harmonize the best practices for achieving wrist-watches global regulatory chemical compliance.

It is reasonable to assume that the wrist-watch is a low risk product for the consumer.

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Horology — Harmonized practices to demonstrate chemical regulatory compliance of wrist-watches

1 Scope

This document proposes harmonized practices with the aim of assisting stakeholders to demonstrate chemical compliance of wrist-watches and their components, according to worldwide products regulations and trade practices.

It provides an efficient rule of application for regulators who set up new regulations.

2 Normative references

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

ISO/IEC 17000, *Conformity assessment — Vocabulary and general principles*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply. If not defined hereinafter, the term and definitions from ISO/IEC 17000 prevail.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

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

— IEC Electropedia: available at https://www.electropedia.org/

3.1
manufacturer
natural or legal person who manufactures a wrist-watch or who has a wrist-watch designed or manufactured and markets it under his name or trademark

[SOURCE: DIRECTIVE 2011/65/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment — modified.]

3.2
economic operator
manufacturer (3.1), authorised representative, importer, distributor, fulfilment service provider or any other natural or legal person who is subject to obligations in relation to the manufacture of wrist-watches, making them available on the market or putting them into service in accordance with the relevant legislation

[SOURCE: Regulation (EU) 2019/1020 of the European parliament and of the Council of 20 June 2019 on market surveillance and compliance of products and amending Directive 2004/42/EC and Regulations (EC) No 765/2008 and (EU) No 305/2011— modified.]

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3.3
compliance technical folder
compilation of all relevant evidence documents supporting the compliance of the wrist-watch

Note 1 to entry: This compilation includes documents concerning the chemical composition (such as material safety data sheet or casting certificates) and/or testing reports.

3.4
watch
timekeeping instrument designed to be worn and to function in all positions

[SOURCE: ISO 6426-2]

3.5
wrist-watch
watch (3.4) to be worn on the wrist

Note 1 to entry: The wrist-watch includes the watch head and the *band* (3.8).

3.6
supplier declaration
procedure by which a supplier gives written assurance that a product, process or service conforms to specified requirements

Note 1 to entry: The supplier declaration can be in accordance to ISO/IEC 17050 (all parts).

3.7
competent
able to apply knowledge and skills to achieve intended results

[SOURCE: IWA 42:2022, 3.4.5]

3.8
band
component permitting to put the watch on the wrist and adapts its length to the wrist dimension

Note 1 to entry: The band is generally made of two parts joined each other by a buckle, permitting to put the watch on the wrist.

Note 2 to entry: The term wristlet is a deprecated term no more used.

Note 3 to entry: The term bracelet is mainly used for metallic bands.

Note 4 to entry: The term strap is also used.

4 Requirements regarding the technical documentation, test reports and self-declaration of conformity

4.1 General

It is reasonable to assume that the wrist-watch is a low risk product for the consumer.

The technical documentation, test reports and self-declaration of conformity shall be written either in English or in one of the official languages of the manufacturer's country.

4.2 Conformity assessment

4.2.1 Conditions of test performed to assess the compliance

It should firstly be defined whether the tests are realised on a finished wrist-watch or a part of it. Sample shall be representative of the wrist-watch placed on the market.

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