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Ophthalmic optics — Spectacle frames — Method for the simulation of wear and detection of nickel release from metal and combination spectacle frames

*Optique ophtalmique — Montures de lunettes — Méthode de
simulation de l'usure et de détection de la libération du nickel de
montures de lunettes en métal et combinées*



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Foreword

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

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The committee responsible for this document is ISO/TC 172, *Optics and photonics*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

This third edition cancels and replaces the second edition (ISO/TS 24348:2007), which has been technically revised.

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Introduction

Adverse skin reaction to nickel has been known for many decades. Nickel is now the most frequent cause of contact allergy, and a significant proportion of the female population is allergic to nickel. Skin absorption of nickel ions, which are released from some nickel-containing materials in direct and prolonged contact with the skin, causes sensitization. Further exposure to soluble nickel salts results in allergic contact dermatitis. It is known that sensitization to nickel requires higher exposure levels than does the elicitation in already sensitized individuals. There is a large variation in the degree of sensitivity to nickel between individuals.

This widespread health problem has forced the introduction of a number of measures designed to reduce its prevalence. They include this Technical Specification which provides two procedures for testing those parts of metal and combination spectacle frames that come into direct and prolonged contact with the skin.

[Clause 4](#) specifies a method for accelerated wear to simulate two years' use of coated metal and combination spectacle frames. The coatings might include rolled gold covering, electro- and other plating methods, varnish and other organic treatments. [Clause 5](#) attempts to provide an *in vitro* chemical test that correlates as far as possible with the variable human biological reactions that occur when metallic articles containing nickel are in direct and prolonged contact with the skin. It provides a measure of the amount of nickel release from a spectacle frame when immersed for one week in artificial sweat.

Clinical patch-testing of a selection of nickel-containing alloys and coatings on nickel-sensitized persons indicates that high and low results achieved with the analytical method in this Technical Specification correspond closely with patch-test reactivity. Moreover, a nickel release rate threshold of 0,5 µg/cm²/week was set in the European Parliament and Council, originally in Directive 94/27/EC (OJ No. L188 of 1994-07-22) and transferred to Regulation (EC) 1907/2006 (OJ No. L396/1 of 2006-12-30, REACH). [\[6\]](#) In order to ensure that articles yielding values near this figure are not unnecessarily excluded from European trade as a result of the difficulties inherent in the test method, particularly when applied to intricately shaped articles, the measured release figures are multiplied by a factor of 0,1. Materials recognized as causing sensitization to nickel would not become acceptable by use of this adjustment. Application of this Technical Specification is confidently expected to significantly reduce the development of allergic contact dermatitis due to nickel.

NOTE Experience of its use and further epidemiological and clinical research can justify changes to test procedure and/or interpretation of the test result