### INTERNATIONAL STANDARD

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# Traditional Chinese medicine — Test method of single-use acupuncture needles for electrical stimulation

Médecine traditionnelle chinoise — Méthode d'essai pour les aiguilles d'acuponcture à usage unique pour la stimulation électrique

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#### Foreword

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This document was prepared by Technical Committee ISO/TC 249, *Traditional Chinese medicine*.

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#### Introduction

Electro-acupuncture is a form of acupuncture treatment that is used in many parts of the world. However, the electrical current produced by the electrical acupuncture stimulator could cause corrosion of the acupuncture needles. There are also some reports regarding possible harm to patients as a result of acupuncture needle corrosion and corrosion residuals. Therefore, it is necessary to check the corrosion resistance of the needles to ensure the safety of patients.

However, ISO 17218 does not include a test method for determining the corrosion resistance of needles used in electro-acupuncture treatment.

This document establishes a uniform test method with simulated body fluid to characterize the corrosion resistance of acupuncture needles to be used in electro-acupuncture treatment.

The use of this test method can provide useful data for comparison of different devices, materials, designs or manufacturing processes. However, it cannot provide safety information for real clinical practices. This in vitro test method is intended for artificial body fluids used for other similar standards, but the round-robin test to verify the validity and repeatability has not been done, and there are no studies on human subjects in clinical practice yet.

Accordingly, the result of this test method cannot be used to evaluate the safety of needles for clinical use and does not determine the quality of needles in clinical use directly.

The ultimate aim of this document is to protect patients who receive electro-acupuncture treatment from the potential risk of the side-effects of needle corrosion caused by electrical conduction.

This document is a necessary step toward establishing a guideline for the safe use of electro-acupuncture in clinics when a correlation between the human body and the simulated body fluid is known in the future.

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