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AMENDMENT 1
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Biological evaluation of medical devices —

Part 10:
Tests for irritation and delayed-type hypersensitivity

AMENDMENT 1

Évaluation biologique des dispositifs médicaux —

Partie 10: Essais d'irritation et d'hypersensibilité retardée

AMENDEMENT 1

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Foreword

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Amendment 1 to ISO 10993-10:2002 was prepared by Technical Committee ISO/TC 194, *Biological evaluation of medical devices*.

Biological evaluation of medical devices —

Part 10:
Tests for irritation and delayed-type hypersensitivity

AMENDMENT 10

Page 1, Clause 1

In the last paragraph, replace “used intradermally in the ocular, oral, rectal, penile and vaginal areas” by the following:

“used intradermally and in the ocular, oral, rectal, penile and vaginal areas”.

Page 3, definition 3.16

Replace “substance material” by “substance/material”.

Page 4, Clause 4 d)

In the last paragraph, replace the current text by the following:

“A test of positive-control substance for skin sensitisation [7] shall be run in a minimum of ten test animals and five control animals at least every six months by the testing laboratory to verify the test system and demonstrate a positive response.”

Add to 4 d) last paragraph a NOTE:

NOTE Fewer animals may be used when an assay with a positive control substance is performed more frequently than once every six months. It is advisable to use at least five test animals with a positive substance and five control animals.

Page 12, subclause 6.4.4.3.5

Replace first sentence by the following:

“Treatment sites are examined for signs of irritation and the responses are scored immediately after patch removal and at 1 h to 2 h, 24 h, 48 h and 72 h after patch removal.”

Page 13, subclause 6.4.5.3 e)

Replace first dash by the following:

“response rate at 0 h, 1 h to 2 h, 24 h, 48 h and 72 h and at any other times scored.”

Page 16, subclause 7.4.4.2

In the fourth paragraph, replace “ibnduction” by “induction” and replace “move” by “more”

Page 19, subclause 7.5.4.3.1

In the third sentence, delete “consecutive” and substitute “Perform” for “Repeat”

Page 23, Annex B

Change “Informative” to “Normative” and replace the title by “Special irritation tests”.

In Annex B.1, replace text by the following:

“The following special irritation tests exist. These tests are relevant for medical devices intended to be applied to specific areas. If used, a rationale shall be provided for the choice of the test method.”

Page 29, Table B.2

Under “1 Cornea” replace, “Opaque iris visible” by “Opaque, details of iris not visible”.

Page 30, subclause B.4.6

In the first sentence, replace “check” by “cheek”.

Page 31, subclause B.4.8.1

In the first paragraph change “untreated” to “treated”.

Page 35, subclause B.5.8.1

In the first paragraph, change “untreated” to “treated”.

Page 41, Clause C.1

In the second paragraph, replace “Registry of Toxic Effects of Chemical Materials (RTECS)” by “Registry of Toxic Effects of Chemical Substances (RTECS)”.

In the last paragraph, replace “OECD Guideline Draft on Acute Dermal Irritation study in human volunteers” by “OECD Draft Guideline on Acute Dermal Irritation Study in Human Volunteers”.

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