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AMENDMENT 1
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Elastomeric parts for parenterals and for devices for pharmaceutical use —

Part 2: Identification and characterization

AMENDMENT 1

*Éléments en élastomère pour administration parentérale et dispositifs à
usage pharmaceutique —*

Partie 2: Identification et caractérisation

AMENDEMENT 1



Reference number
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Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
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Foreword

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International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

Amendment 1 to ISO 8871-2:2003 was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and injection equipment for medical and pharmaceutical use*.

This amendment specifies an additional infrared (IR) spectroscopy method coupled with an attenuated total reflection device for the characterization of rubber material by obtaining a fingerprint IR spectrum.

ISO 8871 consist of the following parts, under the general title *Elastomeric parts for parenterals and for devices for pharmaceutical use*:

- *Part 1: Extractables in aqueous autoclavates*
- *Part 2: Identification and characterization*
- *Part 3: Determination of released-particle count*
- *Part 4: Biological requirements and test methods*
- *Part 5: Functional requirements and testing*

Elastomeric parts for parenterals and for devices for pharmaceutical use —

Part 2: Identification and characterization

AMENDMENT 1

page iii, Contents

Add the following item to the list after Annex G:

Annex H (informative) **Determination of a fingerprint by surface infrared spectroscopy (ATR, attenuated total reflection)**

page 2, Subclause 3.5

Replace 3.5 by the following:

3.5 Infrared spectrum

A very simple method to create a fingerprint of a rubber material is to record an infrared (IR) spectrum. The two common methods for obtaining an IR spectrum of a rubber material are pyrolysis IR and surface IR/ATR (attenuated total reflectance)-technique.

The pyrolysis IR can be obtained as described in Annex A. The surface IR/ATR can be obtained as described in Annex H. The spectra should be compared to a spectrum obtained by the same IR-method on a reference sample of the material.

In practice, pyrolysis IR requires a time-consuming sample preparation and in addition needs the cautious handling of hazardous vapours and oils.

In contrast to this, the surface IR/ATR offers the possibility to obtain a fingerprint from an elastomeric part with minimum or no sample preparation.

page 19, after Annex G

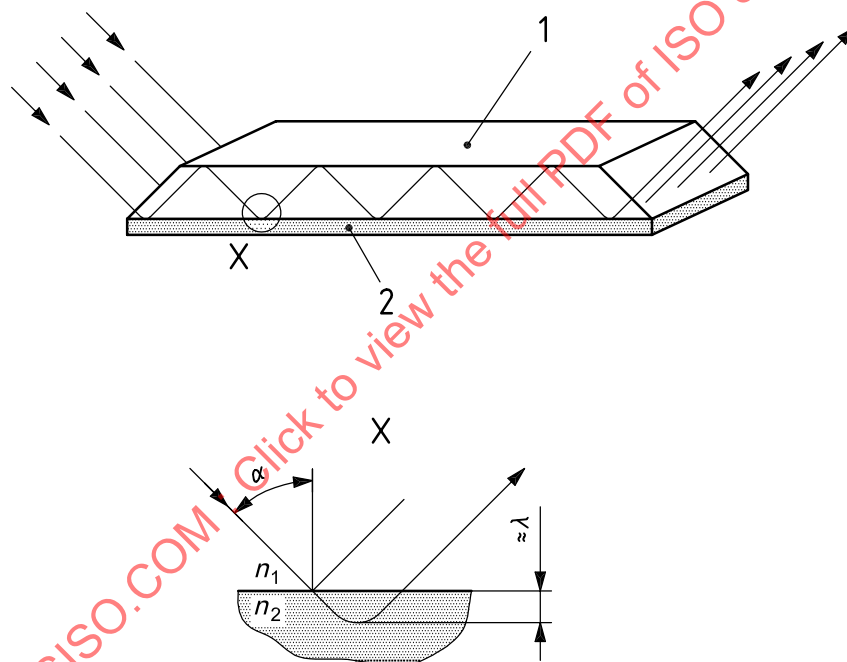
Add a new Annex H as follows:

Annex H (informative)

Determination of a fingerprint by surface infrared spectroscopy (ATR, attenuated total reflection)

H.1 General

The principle of ATR measurement is shown in Figure H.1¹⁾.



Key

- α angle of incident light
- λ wavelength of the radiation used
- n refractive index of crystal (n_1) and test specimen (n_2)
- 1 ATR-crystal
- 2 rubber material (test specimen)

Figure H.1 — Test specimen at the ATR-crystal and pathway of IR-beam

1) For more information refer to relevant literature or ISO surface infrared measurements.