

# INTERNATIONAL STANDARD

# ISO 10555-1

First edition  
1995-06-15

**AMENDMENT 2**  
2004-05-15

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## Sterile, single-use intravascular catheters —

### Part 1: General requirements

#### AMENDMENT 2

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*Cathéters intravasculaires stériles, non réutilisables —*

*Partie 1: Prescriptions générales*

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AMENDEMENT 2



Reference number  
ISO 10555-1:1995/Amd.2:2004(E)

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## Foreword

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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 2 to ISO 10555-1:1995 was prepared by Technical Committee ISO/TC 84, *Devices for administration of medicinal products and intravascular catheters*, Subcommittee SC 1, *Syringes, needles and intravascular catheters for single use*, in order to reflect the increasing supply and usage of catheters having coatings.

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# Sterile, single-use intravascular catheters —

## Part 1: General requirements

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*Page 1, Clause 3*

Add the following definition:

#### **3.11 coating**

any material added to a catheter, in less than pharmacological concentrations, to modify the antithrombotic and/or antimicrobial properties of the catheter

NOTE The coating may be physically and/or chemically bonded to the surface, impregnated into the catheter surface or compounded as a constituent of the catheter material.

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*Page 4, Clause 6* <https://standards.iteh.ai/catalog/standards/sist/c43e563b-6337-4a0d-ba12-be91e649c387/iso-10555-1-1995-amd-2-2004>

Add the following items to the list:

- m) duration of effectiveness in use of any specified coating(s) that have been applied;
- n) if applicable, special claims made because of the presence of the coating;
- o) if applicable, a description of the coating material;
- p) if applicable, the method of coating addition, e.g.
  - applied to the surface,
  - impregnated into the surface,
  - formulated or compounded as a component of the catheter material.
- q) if applicable, known reactions between the catheter and magnetic resonance imaging (MRI);
- r) if applicable, shelf life and storage conditions;
- s) if applicable, any contra-indications, warnings and precautions based on the coating material(s.)

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