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# Sterile intravaskulære kateterindførere, dilatatorer og guidewires til engangsbrug

Sterile single-use intravascular introducers, dilators and  
guidewires – Amendment 1 (ISO 11070:2014/Amd 1:2018)

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ICS: 11.040.25

**Første del af denne publikations betegnelse er:**

**DS/EN ISO, hvilket betyder, at det er en international standard, der har status både som europæisk og dansk standard.**

**Denne publikations overensstemmelse er:**

**IDT med: ISO 11070:2014/Amd 1:2018**

**IDT med: EN ISO 11070:2014/A1:2018**

**DS-publikationen er på engelsk.**

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### **DS-publikationstyper**

Dansk Standard udgiver forskellige publikationstyper.

Typen på denne publikation fremgår af forsiden.

Der kan være tale om:

#### **Dansk standard**

- standard, der er udarbejdet på nationalt niveau, eller som er baseret på et andet lands nationale standard, eller
- standard, der er udarbejdet på internationalt og/eller europæisk niveau, og som har fået status som dansk standard

#### **DS-information**

- publikation, der er udarbejdet på nationalt niveau, og som ikke har opnået status som standard, eller
- publikation, der er udarbejdet på internationalt og/eller europæisk niveau, og som ikke har fået status som standard, fx en teknisk rapport, eller
- europæisk præstandard

#### **DS-håndbog**

- samling af standarder, eventuelt suppleret med informativt materiale

#### **DS-hæfte**

- publikation med informativt materiale

Til disse publikationstyper kan endvidere udgives

- tillæg og rettelsesblade

### **DS-publikationsform**

Publikationstyperne udgives i forskellig form som henholdsvis

- fuldttekstpublikation (publikationen er trykt i sin helhed)
- godkendelsesblad (publikationen leveres i kopi med et trykt DS-omslag)
- elektronisk (publikationen leveres på et elektronisk medie)

### **DS-betegnelse**

Alle DS-publikationers betegnelse begynder med DS efterfulgt af et eller flere præfikser og et nr., fx **DS 383**, **DS/EN 5414** osv. Hvis der efter nr. er angivet et **A** eller **Cor**, betyder det, enten at det er et **tillæg** eller et **rettelsesblad** til hovedstandard, eller at det er indført i hovedstandard.

DS-betegnelse angives på forsiden.

### **Overensstemmelse med anden publikation:**

Overensstemmelse kan enten være IDT, EQV, NEQ eller MOD

- **IDT:** Når publikationen er identisk med en given publikation.
- **EQV:** Når publikationen teknisk er i overensstemmelse med en given publikation, men præsentationen er ændret.
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- **MOD:** Når publikationen er modificeret i forhold til en given publikation.

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Second edition  
2014-11-01  
**AMENDMENT 1**  
2018-05-30

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## **Sterile single-use intravascular introducers, dilators and guidewires**

*Introducteurs, dilatateurs et guides intravasculaires stériles non réutilisables*



Reference number  
ISO 11070:2014/Amd.1:2018(E)

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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see [www.iso.org/directives](http://www.iso.org/directives)).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see [www.iso.org/patents](http://www.iso.org/patents)).

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For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: [www.iso.org/iso/foreword.html](http://www.iso.org/iso/foreword.html).

This document was prepared by Technical Committee ISO/TC 84, *Devices for administration of medicinal products and catheters*.

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## **Sterile single-use intravascular introducers, dilators and guidewires**

*8.6*

Designate the existing NOTE as NOTE 1 and add the following new NOTE:

“NOTE 2 This requirement also applies for guidewires with polymer jackets.”