

# norm

# NEN-EN-ISO 18113-5

Clinical laboratory testing and in vitro diagnostic medical systems - Information supplied by the manufacturer (labelling) - Part 5: In vitro diagnostic instruments for self-testing (ISO/DIS 18113-5:2006, IDT)

Publicatie uitsluitend voor commentaar

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ICS 11.100.10

Commentaar voor 2007-03-30

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November 2006

ICS

Will supersede EN 592:2002

English Version

Clinical laboratory testing and in vitro diagnostic medical systems - Information supplied by the manufacturer (labelling) - Part 5: In vitro diagnostic instruments for self-testing (ISO/DIS 18113-5:2006)

Essais cliniques de laboratoire et systèmes médicaux de diagnostic in vitro - Informations fournies par le fabricant (marquage) - Partie 5: Instruments de diagnostic in vitro pour auto-essais (ISO/DIS 18113-5:2006)

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## Foreword

This document (prEN ISO 18113-5:2006) has been prepared by Technical Committee ISO/TC 212 "Clinical laboratory testing and in vitro diagnostic test systems" in collaboration with Technical Committee CEN/TC 140 "In vitro diagnostic medical devices", the secretariat of which is held by DIN.

This document is currently submitted to the parallel Enquiry.

This document will supersede EN 592:2002.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

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# Clinical laboratory testing and in vitro diagnostic medical systems — Information supplied by the manufacturer (labelling)

## Part 5: In vitro diagnostic instruments for self-testing

*Essais cliniques de laboratoire et systèmes médicaux de diagnostic in vitro — Informations fournies par le fabricant (marquage)*

*Partie 5: Instruments de diagnostic in vitro pour auto-essais*

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