



SLOVENSKI STANDARD

SIST EN 18000-1:2026

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**Diagnostične analize zdravja živali - Nadzor diagnostičnih reagentov in vitro - 1.
del: Vloga za začetno kontrolo in kontrolo od serije do serije**

Animal health diagnostic analyses - Control of in vitro diagnostic reagents - Part 1:
Application file for the initial and the batch-to-batch control

Tiergesundheitsdiagnostische Analysen - Kontrolle von in-vitro-diagnostischen
Reagenzien - Teil 1: Antragsunterlagen für die Erstkontrolle und die Kontrolle von
Charge zu Charge

Analyses de diagnostic en santé animale - Contrôle des réactifs de diagnostic in vitro -
Partie 1 : Dossier de présentation pour le contrôle initial et le contrôle lot à lot

Ta slovenski standard je istoveten z: EN 18000-1:2026

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ICS:

11.100.10	Diagnostični preskusni sistemi in vitro	In vitro diagnostic test systems
11.220	Veterinarstvo	Veterinary medicine

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EUROPEAN STANDARD
NORME EUROPÉENNE
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ICS 11.220

English Version

**Animal health diagnostic analyses - Control of in vitro
diagnostic reagents - Part 1: Application file for the initial
and the batch-to-batch control**

Analyses de diagnostic en santé animale - Contrôle des
réactifs de diagnostic in vitro - Partie 1 : Dossier de
présentation pour le contrôle initial et le contrôle lot à
lot

Tiergesundheitsdiagnostische Analysen - Kontrolle von
in-vitro-diagnostischen Reagenzien - Teil 1:
Antragsunterlagen für die Zulassungs- und die
Chargenprüfung

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
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CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

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European foreword

This document (EN 18000-1:2026) has been prepared by Technical Committee CEN/TC 469 “Animal health diagnostic analyses”, the secretariat of which is held by AFNOR.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by July 2026, and conflicting national standards shall be withdrawn at the latest by July 2026.

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