

DIN EN 18000-1:2026-07 (E)

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

Contents		Page
European foreword		3
Introduction		4
1	Scope	5
2	Normative references	5
3	Terms and definitions	5
4	General control steps and prerequisites	14
5	Content of the file for the initial control	14
5.1	General	14
5.2	Administrative information	15
5.2.1	General	15
5.2.2	Presentation	15
5.3	Technical file of the reagent	16
5.3.1	Manufacture	16
5.3.2	Assessment file	17
5.4	References	19
6	Content of the file for batch-to-batch control	20
6.1	General	20
6.2	Written batch control request	20
6.3	Results of the applicant's internal quality control	20
7	Conformity certificates	20
8	Modifications of a reagent	21
8.1	Control organization and end users information	21
8.2	Management of major and minor modifications by the control organization	21
Annex A (normative) Description form and label of a reference material		22
Annex B (normative) File to be compiled by the applicant for the assessment of a reagent by a control organization		24
Annex C (normative) Declaration of interest		28
Annex D (normative) Reagent or batch conformity certificate issued by the control organization		29
Annex E (normative) Notification of a reagent modification		30
Bibliography		31