

ISO 29942:2011-07 (E)

Prophylactic dams - Requirements and test methods

Contents	Page
Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	2
4 Quality verification	3
5 Design	4
6 Barrier properties	5
7 Biocompatibility	5
8 Surface finish	5
9 Tensile properties	5
10 Tests for stability and shelf-life	6
11 Freedom from holes	7
12 Visible defects	7
13 Packaging and labelling	7
14 Data sheets	10
Annex A (normative) Sampling plans intended for assessing compliance of a continuing series of lots of sufficient number to allow the switching rules to be applied	11
Annex B (normative) Sampling plans intended for assessing compliance of isolated lots	12
Annex C (normative) Determination of length and width	13
Annex D (normative) Determination of dam thickness	14
Annex E (informative) Guidance for risk assessment	15
Annex F (normative) Determination of barrier properties using the bacteriophage method	17
Annex G (normative) Determination of tensile properties	21
Annex H (normative) Oven conditioning	22
Annex I (normative) Determination of shelf-life by real-time stability studies	23
Annex J (informative) Guidance on conducting and analysing accelerated ageing studies	25

Annex K (normative) Testing for holes	27
Bibliography	29