INTERNATIONAL STANDARD

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Implants for surgery — Copolymers and blends based on polylactide — *In vitro* degradation testing

Implants chirurgicaux — Copolymères et mélanges à base de polylactide — Essais de dégradation in vitro

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Contents

International Organization for Standardization
Case postale 56 • CH-1211 Genève 20 • Switzerland
Internet iso@iso.ch

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 3.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

International Standard ISO 15814 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 1, *Materials*.

Annex A of this International Standard is for information only.

Implants for surgery — Copolymers and blends based on polylactide — *In vitro* degradation testing

1 Scope

This International Standard is applicable to copolymers and/or blends based on polylactide, in bulk or processed forms, used for the manufacture of surgical implants.

This International Standard describes methods for the determination of chemical and mechanical changes in the properties of these copolymers and/or blends under *in vitro* degradation testing conditions.

The test methods specified in this International Standard are intended to determine the degradation rate and the changes in material properties of polylactide-based copolymers and/or blends with various comonomers (for example glycolid, trimethylene carbonate, ε-caprolactone) *in vitro*. These *in vitro* methods cannot be used to predict definitely the behaviour of these materials under in *vivo* conditions.

The purpose of this International Standard is to compare and/or evaluate materials or processing conditions.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 178:1993, *Plastics — Determination of flexural properties.*

ISO 180:1993, *Plastics — Determination of Izod impact strength.*

ISO 527-1:1993, *Plastics — Determination of tensile properties — Part 1: General principles.*

ISO 527-2:1993, *Plastics — Determination of tensile properties — Part 2: Test conditions for moulding and extrusion plastics.*

ISO 537:1989, *Plastics — Testing with the torsion pendulum.*

ISO 604:1993, *Plastics — Determination of compressive properties.*

ISO 1184:1993, *Plastics — Determination of tensile properties of films.*

ISO 1628-1:1998, *Plastics — Determination of the viscosity of polymers in dilute solution using capillary viscometers — Part 1: General.*

ISO 1805:1973, *Fishing nets — Determination of breaking load and knot breaking load of netting yarns.*

ISO 2062:1993, *Textiles — Yarns from packages — Determination of single-end breaking force and elongation at break.*

ISO 3696:1987, *Water for analytical laboratory use — Specification and test methods*.

ISO 5081:1977, *Textiles — Woven fabrics — Determination of breaking strength and elongation (Strip method).*

ISO/TR 10993-9:1994, *Biological evaluation of medical devices — Part 9: Framework for identification and quantification of potential degradation products.*

ISO 13781:1997, *Poly(L-lactide) resins and fabricated forms for surgical implants — In vitro degradation.*

ISO 14130:1997, *Fibre-reinforced plastic composites — Determination of apparent interlaminar shear strength by short-beam method*.

3 Terms and definitions

For the purposes of this International Standard, the terms and definitions given in ISO 13781, ISO/TR 10993-9 and the following apply.

3.1
copolymer
polymeric material which consists of different monomer units

3.2
blend
polymeric material which consists of different polymers mixed intensively together

3.3
resorption
loss of morphology and loss of mass

4 Degradation methods

4.1 General

The initial values for the following tests shall be determined directly before starting the degradation test (time zero). The tests shall be carried out on the degraded samples at each test period.

4.2 Reagents and apparatus

4.2.1 Soaking solution (phosphate buffer solution; Sörensen buffer)

For the *in vitro* degradation study, the test sample shall be immersed in a ”Sörensen” buffer solution (pH 7,4) consisting of potassium dihydrogenphosphate and disodium hydrogenphosphate in analytical water Grade 2 in accordance with ISO 3696.

a) 1/15 mol/l KH_2PO_4: 9,078 g KH_2PO_4 per litre H_2O

b) 1/15 mol/l Na_2HPO_4: 11,876 g $Na_2HPO_4 \cdot 2H_2O$ per litre H_2O

Prepare the solution by mixing 18,2 % (volume fraction) from solution a) and 81,8 % (volume fraction) from solution b).

No other additives shall be used for the solution.