

Biological evaluation of medical devices —

Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity

The European Standard EN 30993-3:1993 has the status of a
British Standard

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National foreword

This Part of BS EN 30993 has been prepared under the direction of the Health Care Standards Policy Committee and is the English language version of EN 30993-3 *Biological evaluation of medical devices — Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity*, published by the European Committee for Standardization (CEN). It is identical with ISO 10993-3:1992 *Biological evaluation of medical devices — Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity*, published by the International Organization for Standardization (ISO). EN 30993-3 was produced as a result of international discussions in which the United Kingdom took an active part.

Part 1 of BS EN 30993 provides guidance on the selection of tests for the initial assessment of biological hazards in medical devices.

For in vivo tests, attention is drawn to the provisions of the Animals (Scientific Procedures) Act 1986.

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Summary of pages

This document comprises a front cover, an inside front cover, pages i and ii, the EN title page, pages 2 to 8, an inside back cover and a back cover.

This standard has been updated (see copyright date) and may have had amendments incorporated. This will be indicated in the amendment table on the inside front cover.

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English version

Biological evaluation of medical devices — Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity

(ISO 10993-3:1992)

Essais biologiques des matériaux médicaux —
Partie 3: Essais concernant la génotoxicité, la
cancerogénicité et la toxicité sur la
reproduction
(ISO 10993-3:1992)

Biologische Beurteilung von
Medizinprodukten —
Teil 3: Prüfungen auf Gentoxizität,
Karzinogenität und Reproduktionstoxizität
(ISO 10993-3:1992)

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