International Standard

ISO 23317

Implants for surgery — Materials — Simulated body fluid (SBF) preparation procedure and test method to detect apatite formation in SBF for initial screening of bone-contacting implant materials

Implants chirurgicaux — Matériaux — Mode opératoire de préparation de fluide corporel simulé (FCS) et méthode d'essai pour détecter la formation d'apatite dans le FCS pour l'étude préliminaire de matériaux d'implant en contact avec l'os

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Foreword

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This document was prepared by Technical Committee ISO/TC 150, *Implants or surgery*, Subcommittee SC 1, *Materials*.

This fourth edition cancels and replaces the third edition (ISO 23317:2014), which has been editorially revised. The main changes are:

— the title, Introduction and scope have been revised to clarify the significance and limitations of the SBF test;

— the terms and definitions clause has been rearranged and revised for better understanding;

— the list of apparatus and materials has been enriched and detailed;

— the test specimen preparation has been revised, and test specimen characterization has been added;

— the preparation of SBF has been revised and described in more detail;

— a description of test specimens with lower density than SBF has been added;

— the arrangement of the test specimen in the SBF test has been revised and explained depending on the specimen's shape and density;

— the necessity of visual inspection of SBF has been added;

— the soaking period of seven days in the SBF test has been specified;

— the criteria for judging the specimen's apatite-forming ability in the SBF test have been clarified;

— the test report has been detailed according to the revised SBF test procedure;

— the bibliography has been revised and each bibliographical entry has been cited at the relevant point in this document.

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