

PD ISO/TS 19218-2:2012



BSI Standards Publication

Medical devices — Hierarchical coding structure for adverse events

Part 2: Evaluation codes

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National foreword

This Published Document is the UK implementation of ISO/TS 19218-2:2012. Together with DD ISO/TS 19218-1:2011, it supersedes DD ISO/TS 19218:2005, which is withdrawn.

The UK participation in its preparation was entrusted by Technical Committee CH/210, Quality management and corresponding general aspects for medical devices, to Subcommittee CH/210/3, General terminology and symbols for Medical Devices.

A list of organizations represented on this committee can be obtained on request to its secretary.

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Medical devices — Hierarchical coding structure for adverse events —

Part 2: Evaluation codes

*Dispositifs médicaux — Structure de codage pour la cause et le type
d'événement défavorable —*

Partie 2: Codes d'évaluation



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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.

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The main task of technical committees is to prepare International Standards. 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.

In other circumstances, particularly when there is an urgent market requirement for such documents, a technical committee may decide to publish other types of document:

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ISO/TS 19218-2 was prepared by Technical Committee ISO/TC 210, *Quality management and corresponding general aspects for medical devices*.

This first edition of ISO/TS 19218-2, together with ISO/TS 19218-1, cancels and replaces ISO/TS 19218:2005, which has been technically revised.

ISO 19218 consists of the following parts, under the general title *Medical devices — Hierarchical coding structure for adverse events*:

- *Part 1: Event-type codes*
- *Part 2: Evaluation codes*

Introduction

It is envisaged that the adverse-event evaluation codes specified in this part of ISO 19218 will originate primarily from the manufacturer of the device concerned. This Technical Specification provides a structure by which adverse-event evaluations can be used to collect medical device surveillance information in the post-market phase. It will also enable this information to be easily exchanged on an international basis using the common codes.

It can be used by healthcare providers and other users of the devices; however, a number of the evaluation codes characterize the results of analyses or investigations conducted by the manufacturer or regulatory authorities, who can use it to

- recognize the results of analyses or investigations of adverse events by means of globally recognized evaluation codes, and
- apply these codes as part of a medical device surveillance or reporting system.

Annex A shows how adverse-event codes can be used in conjunction with other data elements in order to facilitate global data exchange between regulatory bodies.