

INTERNATIONAL STANDARD

**ISO
10310**

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Neurosurgical implants — Marking and packaging of implantable neural stimulators

*Implants neurochirurgicaux — Marquage et emballage des
neurostimulateurs implantables*



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Contents

	Page
1 Scope	1
2 Definitions	1
3 Device identification	2
4 Packaging	2
5 Package marking	2
6 Accompanying documentation	3
 Annex	
A Rationale	6

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.

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 10310 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 3, *Neurosurgical implants*.

Annex A of this International Standard is for information only.

Introduction

The purpose of this International Standard is to ensure that the neural stimulator (including implant pulse generators and implant RF receivers) or component thereof is adequately packaged and that the device and packaging are labelled with sufficient information. This information needs to be readily available to the clinician and patient so as to facilitate decision-making on such matters as the choice of device, the methods of implantation, adjustment and fault diagnosis, and to convey user precautions.

It is recommended that implantable neural stimulators and components are manufactured in accordance with the ISO 9000 series of Quality Standards and under international or national good manufacturing practices where these exist.

Work on a general standard for active implants (implantable devices with power sources) is under way in CEN/CENELEC with liaison from IEC/SC62D and ISO/TC 150 work.

The contents of this International Standard will be reflected in that work. A subsequent standard that will cover all aspects of neural stimulators will be developed to replace this limited scope standard once the general standard is available.