TECHNICAL SPECIFICATION

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English Version

Non-active surgical implants - Injectable implants

Nichtaktive chirurgische Implantate - Injizierbare Implantate

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Contents

Page

Foreword

This document (CEN/TS 15277:2006) has been prepared by Technical Committee CEN/TC 285 “Non-active surgical implants”, the secretariat of which is held by NEN.

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Introduction

This Technical Specification has been written because injectable implants are not covered by any standard.

1 Scope

This Technical Specification gives characteristics of medical devices that are injectable implants, such as lifetime, migration, displacement, unintended degradation, impurity, infections, bio-incompatibility and clinical incompatibility.

Pharmaceuticals, e.g. Botulinum-toxin, are not covered by the present document.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

EN ISO 10993, *Biological evaluation of medical devices (all parts)*

EN ISO 14155-1, *Clinical investigation of medical devices for human subjects – Part 1: General requirements (ISO 14155-1:2003)*

EN ISO 14155-2, *Clinical investigation of medical devices for human subjects – Part 2: Clinical investigation plans (ISO 14155-2:2003)*

EN ISO 14630:1997, *Non-active surgical implants – General requirements (ISO 14630:1997)*

EN ISO 14971 *Medical devices - Application of risk management to medical devices (ISO 14971:2000)*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
biocompatibility
ability of a material to perform with an appropriate host response in a specific application.

NOTE This would be restricted to in vitro tests etc.]

3.2
clinical compatibility
Absence of unacceptable risk due to the implant as documented during pre-market and post-market evaluation

NOTE For acceptability of risk see EN ISO 14971

3.3
degradation
decomposition of an injectable implant in vivo into smaller chemical or physical components

3.4
displacement
undesired dislocation of the implant due to mechanical forces or gravity

3.5
impurity
unacceptable levels of substances from the production process and/or of other substances in injectable implants