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DIN EN ISO 8871-4

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Elastomeric parts for parenterals and for devices for pharmaceutical use –
Part 4: Biological requirements and test methods (ISO 8871-4:2006)
English version of DIN EN ISO 8871-4:2006-09

Elastomere Teile für Parenteralia und für Geräte zur pharmazeutischen Verwendung –
Teil 4: Biologische Anforderungen und Prüfverfahren (ISO 8871-4:2006)
Englische Fassung DIN EN ISO 8871-4:2006-09

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National foreword

This standard has been published in accordance with a decision taken by CEN/CMC to adopt, without alteration, International Standard ISO 8871-4 as a European Standard.

The responsible German body involved in its preparation was the *Normenausschuss Medizin* (Medical Standards Committee), Technical Committee 063-02-15 *Gummi*.

DIN EN ISO 8871 consists of the following parts, under the general title "Elastomeric parts for parenterals and for devices for pharmaceutical use":

— *Part 1: Extractables in aqueous autoclavates*

— *Part 2: Identification and characterization*

— *Part 3: Determination of released-particle count*

— *Part 4: Biological requirements and test methods*

— *Part 5: Functional requirements and testing*

The DIN Standards corresponding to the International Standards referred to in the EN are as follows:

ISO 10993-5	DIN EN ISO 10993-5
ISO 11737-1	DIN EN ISO 11737-1

National Annex NA
(informative)

Bibliography

DIN EN ISO 10993-5, *Biological evaluation of medical devices — Part 5: Tests for cytotoxicity: in vitro-methods*

DIN EN ISO 11737-1:2006-06, *Sterilization of medical devices — Microbiological methods — Part 1: Determination of a population of microorganisms on products (ISO 11737-1:2006)*

EUROPEAN STANDARD

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English Version

Elastomeric parts for parenterals and for devices for pharmaceutical use - Part 4: Biological requirements and test methods (ISO 8871-4:2006)

Éléments en élastomère pour administration parentérale et dispositifs à usage pharmaceutique - Partie 4: Exigences biologiques et méthodes d'essais (ISO 8871-4:2006)

Elastomere Teile für Parenteralia und für Geräte zur pharmazeutischen Verwendung - Teil 4: Biologische Anforderungen und Prüfverfahren (ISO 8871-4:2006)

This European Standard was approved by CEN on 5 June 2006.

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This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Central Secretariat has the same status as the official versions.

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