



BSI Standards Publication

Elastomeric parts for parenterals and for devices for pharmaceutical use

Part 3: Determination of released-particle count

National foreword

This British Standard is the UK implementation of EN ISO 8871-3:2004+A1:2019. It is identical to ISO 8871-3:2003, incorporating amendment 1:2018. It supersedes BS EN ISO 8871-3:2004, which is withdrawn.

The start and finish of text introduced or altered by amendment is indicated in the text by tags. Tags indicating changes to ISO text carry the number of the ISO amendment. For example, text altered by ISO amendment 1 is indicated by A1 A1.

The UK participation in its preparation was entrusted to Technical Committee CH/212, IVDs.

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

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Amendments/corrigenda issued since publication

Date	Text affected
30 April 2019	Implementation of ISO amendment 1:2018 with CEN endorsement A1:2019

English Version

**Elastomeric parts for parenterals and for devices for
pharmaceutical use - Part 3: Determination of released-
particle count**

Éléments en élastomère pour administration
parentérale et dispositifs à usage pharmaceutique
- Partie 3: Détermination des particules libérées

Elastomere Teile für Parenteralia und für Geräte
zur pharmazeutischen Verwendung - Teil 3:
Bestimmung von herausgelösten Partikeln

This European Standard was approved by CEN on 1 April 2004.

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European foreword

The text of ISO 8871-3:2003 has been prepared by Technical Committee ISO/TC 76 "Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use" of the International Organization for Standardization (ISO) and has been taken over as EN ISO 8871-3:2004 by CMC.

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Endorsement notice

The text of ISO 8871-3:2003 has been approved by CEN as EN ISO 8871-3:2004 without any modifications.

Foreword to amendment A1

The text of ISO 8871-3:2003/Amd 1:2018 has been prepared by Technical Committee ISO/TC 76 "Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use" of the International Organization for Standardization (ISO) and has been taken over as EN ISO 8871-3:2004/A1:2019 by Technical Committee CEN/TC 205 "Non-active medical devices" the secretariat of which is held by DIN.

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Endorsement notice

The text of ISO 8871-3:2003/Amd 1:2018 has been approved by CEN as EN ISO 8871-3:2004/A1:2019 without any modification.

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