

STN	Dielce z elastomérov na parenterálne použitie a pre farmaceutické prístroje Časť 3: Stanovenie výpočtu uvoľnených častíc (ISO 8871-3: 2003) Zmena A1	STN EN ISO 8871-3/A1 85 5225
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Elastomeric parts for parenterals and for devices for pharmaceuticals use - Part 3: Determination of released-particle count (ISO 8871-3:2003)

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 07/19

Obsahuje: EN ISO 8871-3:2004/A1:2019, ISO 8871-3:2003/Amd 1:2018

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 8871-3:2004/A1

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ICS 11.040.20

English Version

**Elastomeric parts for parenterals and for devices for
pharmaceutical use - Part 3: Determination of released-
particle count - Amendment 1 (ISO 8871-3:2003/Amd
1:2018)**

Éléments en élastomère pour administration
parentérale et dispositifs à usage pharmaceutique -
Partie 3: Détermination des particules libérées -
Amendement 1 (ISO 8871-3:2003/Amd 1:2018)

Elastomere Teile für Parenteralia und für Geräte zur
pharmazeutischen Verwendung - Teil 3: Bestimmung
von herausgelösten Partikeln - Änderung 1 (ISO 8871-
3:2003/Amd 1:2018)

This amendment A1 modifies the European Standard EN ISO 8871-3:2004; it was approved by CEN on 29 November 2018.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
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EN ISO 8871-3:2004/A1:2019 (E)

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European foreword

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.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by September 2019, and conflicting national standards shall be withdrawn at the latest by September 2019.

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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.

INTERNATIONAL STANDARD

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AMENDMENT 1
2018-01

Elastomeric parts for parenterals and for devices for pharmaceutical use —

Part 3: Determination of released-particle count

AMENDMENT 1

*Éléments en élastomère pour administration parentérale et dispositifs
à usage pharmaceutique —*

Partie 3: Détermination des particules libérées

AMENDEMENT 1



Reference number
ISO 8871-3:2003/Amd.1:2018(E)

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This document was prepared by ISO/TC 76, *Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use*.

A list of all the parts of ISO 8871 can be found on the ISO website.

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