DIN EN ISO 8536-2

ICS 11.040.20

Supersedes
DIN EN ISO 8536-2:2003-02 and
DIN EN ISO 8536-2
Corrigendum 1:2005-06

Infusion equipment for medical use – Part 2: Closures for infusion bottles (ISO 8536-2:2010) English translation of DIN EN ISO 8536-2:2010-08

Infusionsgeräte zur medizinischen Verwendung –
Teil 2: Stopfen für Infusionsflaschen (ISO 8536-2:2010)
Englische Übersetzung von DIN EN ISO 8536-2:2010-08

Matériel de perfusion à usage médical –
Partie 2: Bouchons pour flacons de perfusion (ISO 8536-2:2010)
Traduction anglaise de DIN EN ISO 8536-2:2010-08

Document comprises 19 pages

Translation by DIN-Sprachendienst.
In case of doubt, the German-language original shall be considered authoritative.

A comma is used as the decimal marker.

National foreword

This standard has been prepared by Technical Committee ISO/TC 76 “Transfusion, infusion and injection equipment for medical and pharmaceutical use” (Secretariat: DIN, Germany) in collaboration with CEN Management Centre (CMC).

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

DIN EN ISO 8536 consists of the following parts, under the general title *Infusion equipment for medical use*:

— *Part 1: Infusion glass bottles*
— *Part 2: Closures for infusion bottles*
— *Part 3: Aluminium caps for infusion bottles*
— *Part 4: Infusion sets for single use, gravity feed*
— *Part 8: Infusion equipment for use with pressure infusion apparatus*
— *Part 9: Fluid lines for use with pressure infusion equipment*
— *Part 10: Accessories for fluid lines for use with pressure infusion equipment*
— *Part 11: Infusion filters for use with pressure infusion equipment*

Further, the DIN ISO 8536 standards series consists of the following parts, under the general title *Infusion equipment for medical use*:

— *Part 5: Burette infusion sets for single use, gravity feed*
— *Part 6: Freeze drying closures for infusion bottles*
— *Part 7: Caps made of aluminium-plastics combinations for infusion bottles*
— *Part 12: Check valves*

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

ISO 48	DIN ISO 48
ISO 3302 (all parts)	DIN ISO 3302 (all parts)
ISO 8536-1	DIN EN ISO 8536-1
ISO 8536-3	DIN ISO 8536-3
ISO 8871-1	DIN EN ISO 8871-1
ISO 8871-4	DIN EN ISO 8871-4
ISO 8871-5	DIN ISO 8871-5
ISO 15378	DIN EN ISO 15378

Amendments

This standard differs from DIN EN ISO 8536-2:2003-02 and DIN EN ISO 8536-2 Corrigendum 1:2005-06 as follows:

a) The scope now expressly states that the dimensional requirements are not applicable to barrier-coated closures.

b) Requirements relating to materials and stability (clauses 5 and 6) have been revised.

c) Subclause 6.4 “Biological requirements” makes reference to ISO 8871-4.

d) The standard (including the content of Corrigendum 1:2003) has been revised in form and substance.

e) The standard has been editorially revised.

Previous editions

DIN ISO 8536-2:1993-04
DIN EN ISO 8536-2:2003-02
DIN EN ISO 8536-2 Corrigendum 1:2005-06
DIN 58363-2: 1974-11, 1978-03
DIN 58363-6: 1974-11, 1978-03
DIN 58363-10: 1974-11, 1978-03
DIN 58363-11: 1974-11, 1978-03
DIN 58363-12: 1975-08
DIN 58367-1: 1975-08, 1984-04, 1986-04

National Annex NA
(informative)

Bibliography

DIN ISO 48, *Rubber, vulcanized or thermoplastic — Determination of hardness (hardness between 10 IRHD and 100 IRHD)*

DIN ISO 3302 (all parts), *Rubber — Tolerances for products*

DIN ISO 8536-2, *Infusion equipment for medical use — Part 3: Aluminium caps for infusion bottles*

DIN ISO 8871-5, *Elastomeric parts for parenterals and for devices for pharmaceutical use — Part 5: Functional requirements and testing*

DIN EN ISO 8536-1, *Infusion equipment for medical use — Part 1: Infusion glass bottles*

DIN EN ISO 8871-1, *Elastomeric parts for parenterals and for devices for pharmaceutical use — Part 1: Extractables in aqueous autoclavates*

DIN EN ISO 8871-4, *Elastomeric parts for parenterals and for devices for pharmaceutical use — Part 4: Biological requirements and test methods*

DIN EN ISO 15378, *Primary packaging materials for medicinal products — Particular requirements for the application of ISO 9001:2000, with reference to Good Manufacturing Practice (GMP)*

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