International Standard

ISO 11040-7

Second edition
2024-06

Prefilled syringes —

Part 7: Packaging systems for sterilized subassembled syringes ready for filling

Seringues préremplies —

Partie 7: Systèmes d'emballage pour les seringues pré-assemblées stérilisées préremplissables

Reference number
ISO 11040-7:2024(en)

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

Page

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO document should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents. ISO shall not be held responsible for identifying any or all such patent rights.

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

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

This second edition cancels and replaces the first edition (ISO 11040-7:2015), which has been technically revised.

The main changes are as follows:

— Clause 3 was updated;

— former Annex B was removed because this specific method for determination of nest deflection was not commonly adopted by the industry;

— former Annex F was removed because the specific measurement method of determining the distance between the edge of the protective bag to rear end of the tub is not commonly adopted by the industry;

— a new Annex E was added to support automated processing;

— in Annex A, Annex B, the existing market ranges and tolerances have been revised and updated because fully automated and/or high-speed processes require smaller variations of certain tolerances;

— Table D.1 for bag sizes was revised. Bags and header bags are combined, and two main groups of bag sizes have been defined based on market experience and future expectations. They were entered into Table D.1 as column “recommended dimensions for 3” and 4” tub and “recommended dimensions for 4” tub”.

A list of all parts in the ISO 11040 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user’s national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

At the start of prefilled syringe processing by the pharmaceutical industry, syringes made of tubing glass were delivered to the pharmaceutical companies in the form of a so called non-sterile “bulkware” only. The process steps such as washing, drying, inner lubrication, sealing the syringe with a closure system, sterilization, as well as filling, and closing were then performed by the pharmaceutical companies. Since their introduction to the market and with the emergence of specialized process equipment, sterilized subassembled syringes have more and more replaced the non-sterile “bulkware” to become the preferred approach for pre-filled syringe filling operations.

In the case of sterilized subassembled syringes ready for filling, responsibility for the aforementioned process steps relevant to the injectable product lies within the manufacturer of the subassembled syringes. Following the assembly of the needle shield on syringes with a staked needle or tip caps for the Luer cone version, the subassembled syringes are placed into so called nests. The nests, in turn, are placed into a plastic tub. The syringes in the nest are protected by means of an insert liner and the tub itself is sealed by a sealing lid (which is currently, and so far, primarily achieved using a porous material). Thus, the tub properly sealed with the sealing lid represents the “sterile barrier system”. The sealed tub is then wrapped into a sealable bag and, thus, ready for sterilization, which is currently, and so far, primarily performed using ethylene oxide.

In this form, the sterilized subassembled syringes ready for filling are delivered to the pharmaceutical companies in a sterile condition where they are processed on suitable machines.

The packaging design and material maintain sterility and should be compatible with the process of the customer. The packaging characteristics, material, thickness, shape, and resistance to deformations among others are such that they maintain, up to the point of use, the integrity of the product and a validated barrier against particulate and bacterial contamination.

The objective is to support the development of standardized equipment with automatic debagging process steps for aseptic processing.

Prefilled syringes —

Part 7: Packaging systems for sterilized subassembled syringes ready for filling

1 Scope

This document specifies a packaging system that is used to deliver sterilized subassembled syringes ready for filling in tubs and nests.

Downstream processes (processes after filling such as in house/outside transport, reprocessing) can result in specific requirements on the packaging system used to deliver sterilized subassembled syringes ready for filling. However, these requirements are not within the scope of this document.

NOTE 1 Glass barrels and sterilized subassembled syringes ready for filling, plunger stoppers, and plastic barrels for injectables are specified in ISO 11040-4, ISO 11040-5 and ISO 11040-6.

NOTE 2 ISO 11607-2 addresses validation requirements of sealing and packaging processes for medical devices.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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.

ISO 11040-1, *Prefilled syringes — Part 1: Glass cylinders for dental local anaesthetic cartridges*

ISO 11040-2, *Prefilled syringes — Part 2: Plunger stoppers for dental local anaesthetic cartridges*

ISO 11040-3, *Prefilled syringes — Part 3: Seals for dental local anaesthetic cartridges*

ISO 11040-4, *Prefilled syringes — Part 4: Glass barrels for injectables and sterilized subassembled syringes ready for filling*

ISO 11040-5, *Prefilled syringes — Part 5: Plunger stoppers for injectables*

ISO 11040-6, *Prefilled syringes — Part 6: Plastic barrels for injectables and sterilized subassembled syringes ready for filling*

ISO 11040-8, *Prefilled syringes — Part 8: Requirements and test methods for finished prefilled syringes*

ISO 11138-1, *Sterilization of health care products — Biological indicators — Part 1: General requirements*

ISO 11138-2, *Sterilization of health care products — Biological indicators — Part 2: Biological indicators for ethylene oxide sterilization processes*

ISO 11138-3, *Sterilization of health care products — Biological indicators — Part 3: Biological indicators for moist heat sterilization processes*

ISO 11138-4, *Sterilization of health care products — Biological indicators — Part 4: Biological indicators for dry heat sterilization processes*

ISO 11138-5, *Sterilization of health care products — Biological indicators — Part 5: Biological indicators for low-temperature steam and formaldehyde sterilization processes*

ISO 11138-7, *Sterilization of health care products — Biological indicators — Part 7: Guidance for the selection, use and interpretation of results*

ISO 11138-8, *Sterilization of health care products — Biological indicators — Part 8: Method for validation of a reduced incubation time for a biological indicator*

ISO 11607-1, *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems*

3 Terms and definitions

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

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
customer
person or organization that could or does receive a product or a service that is intended for or required by this person or organization

[SOURCE: ISO 9000:2015, 3.2.4, modified — Deletion of EXAMPLE and Note 1 to entry.]

3.2
insert liner
sheet to cover the filled nest

3.3
manufacturer
organization or person that manufactures a product

3.4
nest
plastic plate with a defined hole pattern for the suspension of the syringe bodies

3.5
protective bag
plastic bag or sealing around the tub

Note 1 to entry: There can be more than one protective bags around the tub.

3.6
sealing lid
microbial barrier material for sealing the tub

3.7
packaging system
combination of the sterile barrier system and protective packaging

[SOURCE: ISO 11139:2018, 3.192]

3.8
protective packaging
configuration of materials designed to prevent damage to the sterile barrier system and its contents from the time of their assembly until the point of use

[SOURCE: ISO 11139:2018, 3.219]

3.9
sterile barrier system
minimum package that minimizes the risk of ingress of microorganisms and allows aseptic presentation of the sterile contents at the point of use

Note 1 to entry: For packaging systems for sterilized subassembled syringes ready for filling, the sterile barrier system is formed by the assembled tub and sealing lid.

[SOURCE: ISO 11139:2018, 3.272, modified — Adding Note 1 to entry.]

3.10
tub
plastic container to accommodate the filled nest

4 Requirements for the packaging system

4.1 General

4.1.1 The packaging system intended to contain the ready for filling subassembled syringes shall protect the subassembled syringes and their sterile barrier system during handling, distribution and storage, to maintain the sterility as well as the functional and cosmetic characteristics over the claimed shelf-life.

4.1.2 The materials, the sterile barrier system, and the packaging system that enable sterilization, protect the product and maintain sterility until the point of aseptic filling, shall be in accordance with the requirements of ISO 11607-1.

4.1.3 The packaging system shall have acceptable microbiological and particulate levels to support the introduction of the sterilized syringes into an aseptic filling environment and related designated cleanrooms. Requirements should be agreed upon by the manufacturer and the customer.

NOTE The introduction of sterilized packaged syringes into an aseptic filling environment poses a risk of microbiological and/or particulate contamination of the drug product.

4.1.4 Tubs, nests, lids, inserts and protective bags shall allow the necessary process steps of the sterilized subassembled syringes over their shelf-life. The process steps to be considered include, but are not limited to, the following:

a) for tubs including sealing lid and insert liner:
   - lid sealing and lid opening;
   - conveying;
   - nest insertion and extraction;
   - stacking and destacking;
   - sterilization and decontamination.

b) for nests:
   - subassembled syringe insertion (nesting) and removal (denesting);

— filling;

— plunger stopper insertion;

— stacking and destacking;

— sterilization and decontamination.

c) for protective bag:

— sealing;

— folding;

— sterilization and decontamination;

— cutting and opening.

4.1.5 The packaging configuration including the arrangement of the product shall be agreed with the customer to allow for adequate processing.

NOTE The process steps described include those at the premises of the manufacturer and of the customer.

4.2 Nest and tub configuration

4.2.1 Ready for filling subassembled syringes shall be packaged in a plastic nest, which is placed within a plastic tub.

4.2.2 The nest shall maintain distance between the subassembled syringes to protect against breakage during transportation. Depending on a particular subassembled syringe's dimensions, nests can contain different numbers and sizes of cavities.

4.2.3 The subassembled syringes shall be covered with a protective insert liner and the tub shall be sealed with a sealing lid. Once sealed, the tub and lid assembly shall serve as a sterile barrier system to maintain sterility of the contents following sterilization of the packaging system.

4.3 Nest

4.3.1 This subclause covers nests used for sterilized subassembled syringes ready for filling. Nested formats can also be used for plunger stoppers/pistons.

4.3.2 For the nest, the following information shall be provided:

— external dimensions;

— deflection;

— cavities for the syringes;

— centering/lifting features (i.e. openings, columns);

— defined free space where the lifting tool can engage.

4.3.3 The customer and manufacturer shall agree upon the dimensions and tolerances of the finished product as delivered.

NOTE See Annex A.

4.3.4 The design of the nest shall facilitate the insertion and removal of the sterilized subassembled syringes ready for filling [e.g. Luer lock adapter (LLA)-syringes] by adding bevels or other means.

NOTE For information on the design, see Annex A.

4.3.5 The maximum acceptable nest deflection shall be agreed upon by the manufacturer and customer.

4.4 Tub

4.4.1 External dimensions including reinforcements/beads and radii, for tubs, information on dimensions including tolerances shall be shared with the customers based on the customer and manufacturer agreement.

4.4.2 The tub shall allow the sealing of the lid.

4.4.3 If sterilization indicators are applied to the tubs, they shall conform with ISO 11138-1, ISO 11138-2, ISO 11138-3, ISO 11138-4, ISO 11138-5, ISO 11138-7 and ISO 11138-8, ISO 11040-1, ISO 11040-2, ISO 11040-3, ISO 11040-4, ISO 11040-5, ISO 11040-6 and ISO 11040-8, as applicable. The customer and manufacturer shall agree upon the dimensions and tolerances of the finished product as delivered.

NOTE See Annex B.

4.5 Insert liner

4.5.1 The syringes shall be covered by an insert liner as a protection from particles generated during opening. The insert liner shall be, where appropriate, permeable for the sterilization agent (e.g. made of nonwoven material of polyolefin).

4.5.2 The insert liner can consist of several layers in order to ensure sufficient shielding of the glass against electron beam irradiation during the decontamination process. To enable proper removal, the layers should be connected with each other (e.g. by means of sealing points).

4.5.3 Corners may be rounded or chamfered. The shape and dimensions of the insert liner shall match with the protection demands.

4.6 Sealing lid

4.6.1 The sealing lid (e.g. made from nonwoven polyolefin material) shall be sealable to the tub and completely peelable from the tub while minimizing the risk of releasing particles. The seal properties (e.g. seal strength, seal width) and integrity shall be tested in accordance with a validated test method. For examples of test methods, see ISO 11607-1.

4.6.2 The sealing lid should be designed and positioned to ensure sealing lid overhang beyond the edge of the sealing to support peeling without delamination or tearing.

4.6.3 The sealing lid shall be, where appropriate, permeable for the sterilization agent.

4.6.4 The materials and seals shall be compatible with the decontamination processes, as applicable (e.g. electron beam and vaporized hydrogen peroxide), prior to transfer of the packaging into the aseptic filling area.

4.7 Protective bag

4.7.1 The protective bag shall be permanently sealed and shall enable the selected sterilization method. Testing of the seal properties (e.g. seal strength, seal width and integrity) shall be performed in accordance with a validated test method (for examples of test methods, see ISO 11607-1). As a minimum, the protective

bag shall protect the tub or tray from external contaminants such as dust or dirt. It can also be configured as a sterile barrier system to maintain outside tub sterility over its shelf-life or to allow for bioburden control at the time of use.

4.7.2 The materials and seals shall be compatible with the decontamination processes, as applicable (e.g. electron beam disinfection), prior to transfer of the packaging into the aseptic filling area.

4.7.3 The protective bag can consist of a single bag or a double bag. Annex C provides schematic illustrations of examples of protective bag configurations and Annex D provides recommendations for the design and dimension of protective bags. Annex E provides guidance on the positioning of the tub and folding of inner protective bags for tubs packaged in a double bag configuration.

The following information shall be provided as a minimum to the customer (information on dimensions including tolerances).

For single bags:

— bag dimensions (inside and outside);

— width of the sealing joints, in millimetres, their positions and type of sealing;

— material (type and position, i.e. which material is used at which position);

— orientation of the tub inside the bag.

For double bags:

— dimensions of the outer bag;

— width of the sealing joints, in millimetres, and their positions and type of sealing;

— material (type and position, i.e. which material is used at which position) of the outer bag;

— orientation of the tub with the bag inside the outer bag;

— folding of the inner bag.

4.8 Additional information to be provided by the manufacturer

The manufacturer shall provide

— information about specific material types for all packaging system components.

5 Marking of the tub

The tub shall be marked as agreed upon by the manufacturer of the sterilized subassembled syringe ready for filling and the customer. The tub can contain the following information:

a) manufacturer's name;

b) article description;

c) quantity of sterilized subassembled syringes ready for filling;

d) warning “do not use if packaging is damaged”;

e) date of manufacture;

f) manufacturer's batch number;

g) serial number.

NOTE 1 Machine-readable codes support automatic processing and tracking.

NOTE 2 Symbols according to ISO 7000 or ISO 15223-1 can be used.

6 Labelling

The external packaging shall be marked as agreed upon between the manufacturer of the sterilized subassembled syringes ready for filling and the customer and can contain the following information:

a) manufacturer's name;

b) article description;

c) quantity of sterilized subassembled syringes ready for filling;

d) date of manufacture;

e) manufacturer's batch number.

7 Packaging of tubs in trading units/bundles

The packaging system shall provide adequate protection to the product, including the sterile barrier system, through the hazards of handling, distribution, and storage.

NOTE See ISO 11607-1 for guidance on performance testing requirements and references for appropriate testing conditions.

For packing the filled tubs, consideration should be given to product orientation in the pack to avoid jeopardizing the performance of the product.

Storage conditions, including orientation and shelf life of the packaging system, shall be supported by shipping and ageing tests.

Annex A
(informative)

Design of nests

This annex intends to harmonize nests for sterilized subassembled syringes ready for filling, coming to the market, to facilitate the handling and processing of prefilled syringes. For this purpose, Table A.1, Table A.2, and Table A.3 include:

— the market range of nominal dimensions of nests representing the current status of harmonization;

— the recommended range of nominal dimensions that are offered for future harmonization;

— the recommended tolerance reflecting manufacturing tolerances for critical attributes.

The dimensions can be measured by means of tactile or optical measurement systems.

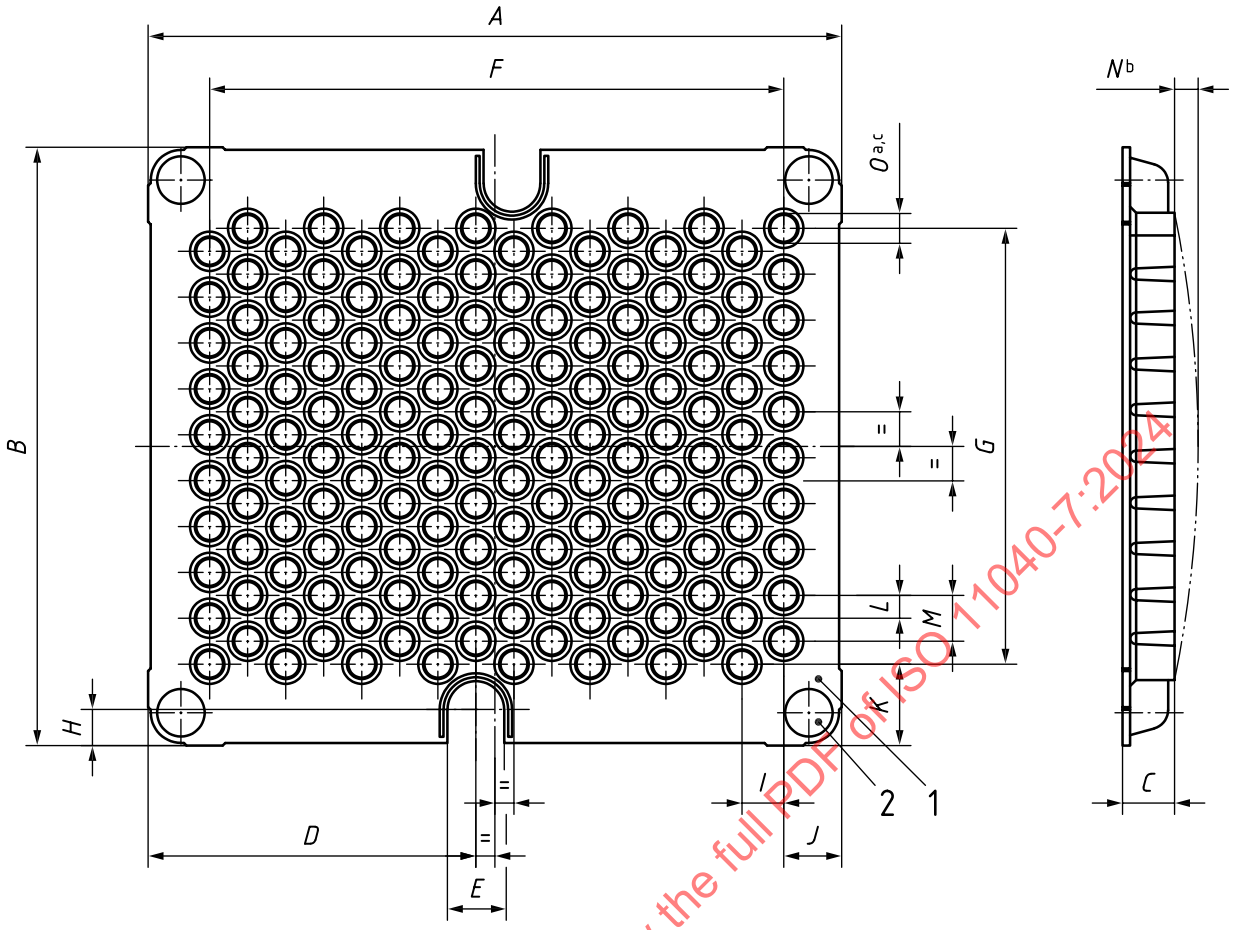
The nest deflection shall be measured when loaded with subassembled syringes ready for filling, supported from the bottom. The related Figure A.1, Figure A.2 and Figure A.3 represent examples of the design of nests. Attention is drawn to the fact that certain designs of flange of plastic syringes of 20 ml and 50 ml, according to ISO 11040-6, do not match with the dimensions given in this annex.

Customers and manufacturers should agree upon the dimensions and tolerances of the finished product as delivered.

Table A.1 — Guidance on dimensions of a 160 cavity nest (see Figure A.1)

Dimensions in millimetres

Position	Market range	Recommended range of nominal dimensions	Recommended tolerance
A	229,2 to 230,8	230,0 to 230,4	—
B	197,5 to 199,1	198,3 to 198,7	—
C	17,3 to 17,7	17,4 to 17,6	—
D	108,2 to 109,3	108,6 to 109,0	—
E	18,5 to 19,5	19,0 to 19,1	—
F	189,7 to 192,3	190,2 to 190,8	±0,5
G	143,8 to 145,0	144,1 to 144,7	±0,5
H	10,8 to 11,8	10,8 to 11,2	—
I	12,5 to 12,9	12,6 to 12,8	±0,2
J	19,65 to 20,25	19,7 to 20,1	—
K	26,8 to 27,3	26,9 to 27,1	—
L	7,5 to 7,7	7,5 to 7,7	±0,2
M	15 to 15,4	15,1 to 15,3	±0,2
N	2,5 max.	0,0 to |1,0|	n.a.
O	9,3 to 9,6	9,3 to 9,5	—
NOTE Measure of N for empty nests delivered to the syringe manufacturers typically show nest deflections of a maximum of 2,5 mm. The range 0,0 to |1,0| mm accounts for nests filled with subassembled syringes.			



Key

1 customized ribbing to reinforce the nest stability against deflection

2 restricted area for suction cups

a 160 × Ø *O* (see Table A.1).

b Maximum deflection (can occur in both directions).

c Cavities are equipped with inside chamfers on both ends to support de- and renesting process.

NOTE 1 Compatible barrel sizes 0,5 ml to 1 ml long.

NOTE 2 Most likely, there are more areas required for suction cups than indicated in the figure.

Figure A.1 — Guidance on design of a 160 cavity nest

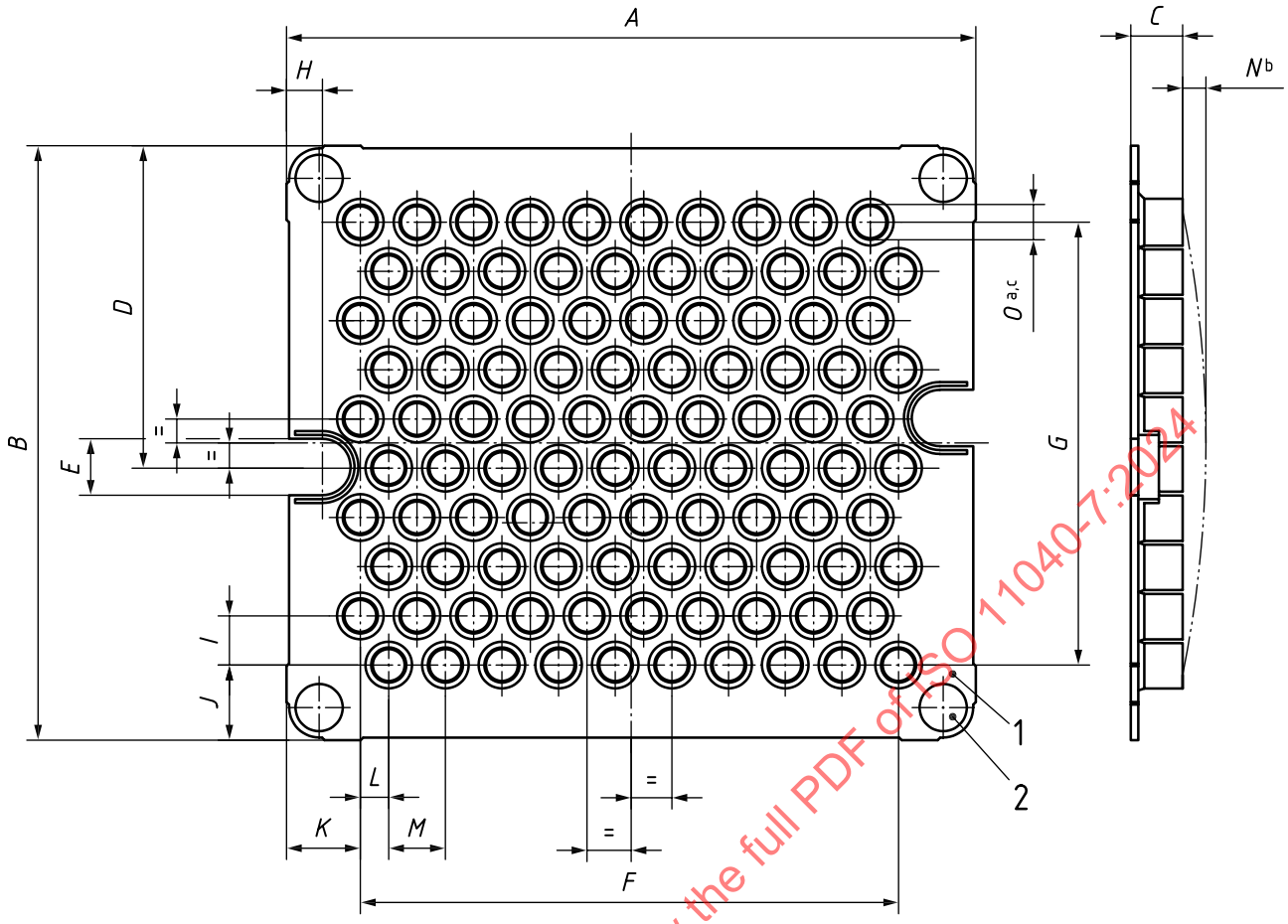
Table A.2 — Guidance on dimensions of a 100 cavity nest (see Figure A.2)

Dimensions in millimetres

Position	Market range	Recommended range of nominal dimensions	Recommended tolerance
A	229,1 to 230,9	230,0 to 230,4	—
B	197,4 to 199,2	198,3 to 198,7	—
C	17,23 to 17,73	17,4 to 17,6	—
D	107,40 to 107,9	107,4 to 107,6	—
E	18,47 to 19,57	19,0 to 19,1	—
F	180,09 to 181,75	180,8 to 181,2	±0,5
G	147,70 to 149,20	148,4 to 148,8	±0,5
H	9,98 to 11,2	10,3 to 10,4	—
I	16,2 to 16,8	16,4 to 16,6	±0,2
J	24,6 to 25,3	24,9 to 25,0	—
K	24,3 to 24,9	24,5 to 24,7	—
L	9,3 to 9,8	9,5 to 9,6	±0,2
M	18,8 to 19,3	19,0 to 19,1	±0,2
N	2,5 max.	0 to |1,0|	n.a.
O (1)	11,98 to 12,42	12,1 to 12,3	—
O (2)	10,3 to 10,5	9,3 to 9,5	—

Note 1 *O* (1) and *O* (2) reflect nests for different syringe dimensions (1 ml-long syringes and 1 ml to 3 ml-long syringes).

Note 2 Measure of *N* for empty nests delivered to the syringe manufacturers typically show nest deflections of a maximum of 2,5 mm. The range 0,0 to |1,0| mm accounts for nests filled with subassembled syringes.



Key

1 customized ribbing to reinforce the nest stability against deflection

2 restricted area for suction cups

a 100 × Ø O (see Table A.2).

b Maximum deflection (can occur in both directions).

c Cavities are equipped with inside chamfers on both ends to support de- and renesting process.

NOTE 1 Compatible barrel sizes 1 ml to 3 ml-long.

NOTE 2 Most likely, there are more areas required for suction cups than indicated in the figure.

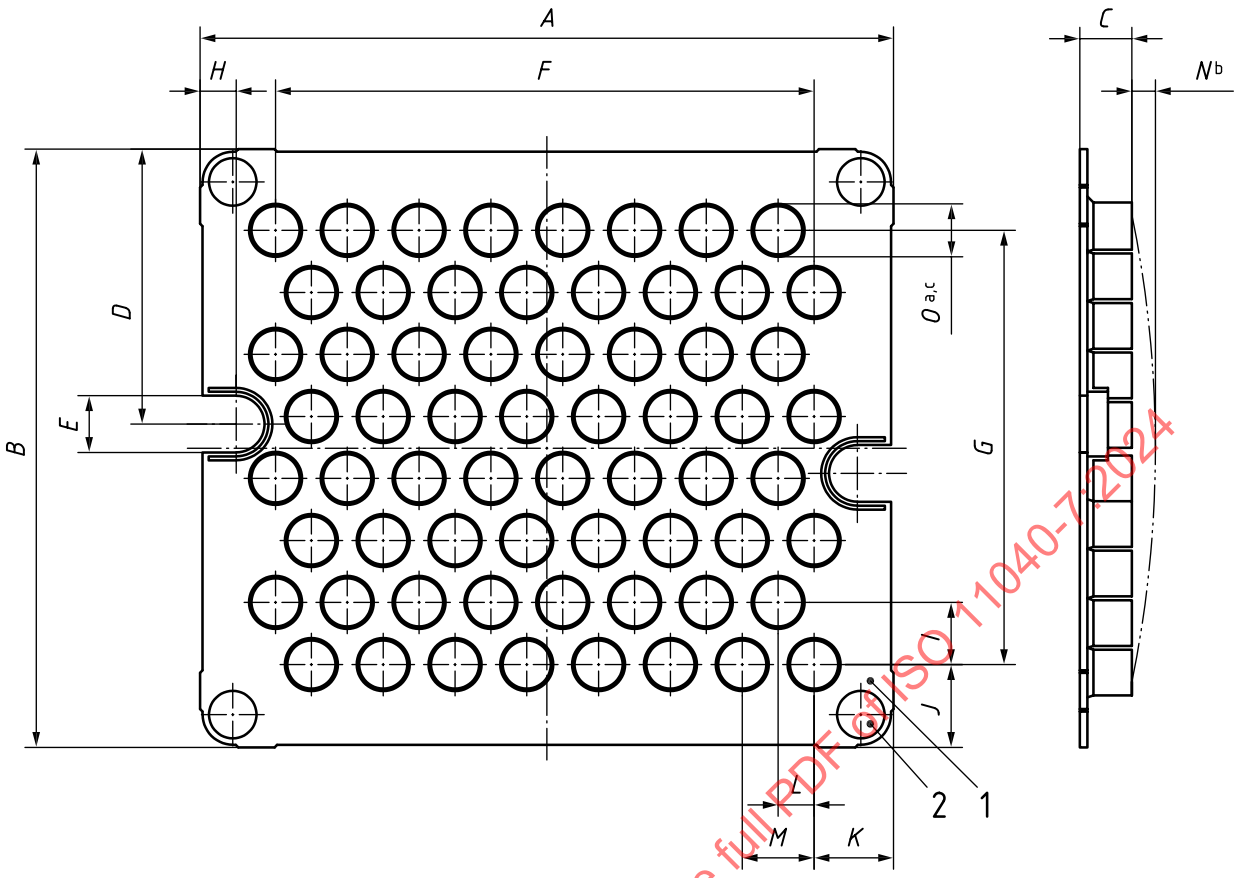
Figure A.2 — Guidance on design of a 100 cavity nest

Table A.3 — Guidance on dimensions of a 64, 42, 30, and 20 cavity nest (see Figure A.3)

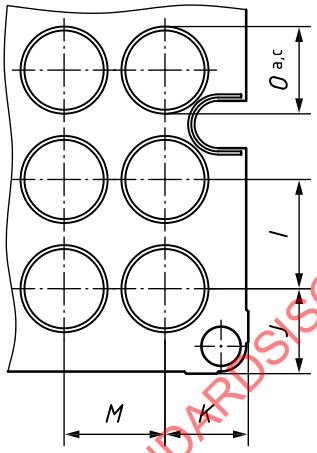
Dimensions in millimetres

	5 ml/64 cavities		10 ml/42 cavities		20 ml/30 cavities		50 ml/20 cavities	
	Recommen-ded range of nominal dimensions	Recom-mend-ed tolerance	Recommend-ed range of nominal dimensions	Recom-mend-ed tolerance	Recommen-ded range of nominal dimensions	Recom-mend-ed tolerance	Recommended range of nominal dimensions	Recom-mend-ed tolerance
A	230,0 to 230,4	—	229,2 to 230,4	—	229,2 to 230,4	—	230,0 to 230,4	—
B	198,3 to 198,7	—	197,4 to 198,7	—	197,6 to 198,7	—	198,3 to 198,7	—
C	17,3 to 17,7	—	17,3 to 17,7	—	22,3 to 22,7	—	17,5 to 23,2	—
D	88,0 to 88,9	—	98,6 to 99,4	—	82,0 to 82,6	—	99,0 to 99,2	—
E	18,8 to 19,1	—	18,8 to 19,1	—	19,0 to 19,1	—	19,0 to 19,1	—
F	180,4 to 181,0	±0,5	171,0 to 171,6	±0,5	166,6 to 167,2	±0,5	158,6 to 164,1	±0,5
G	144,9 to 145,6	±0,5	142,3 to 143,0	±0,5	133,4 to 133,7	±0,5	130,0 to 132,1	±0,5
H	9,5 to 9,7	—	10,6 to 10,8	—	9,4 to 9,6	—	9,4 to 9,6	—
I	20,7 to 20,9	±0,2	28,4 to 28,7	±0,2	33,3 to 33,5	±0,2	43,3 to 44,1	±0,2
J	26,4 to 26,6	—	27,5 to 28,0	—	32,2 to 32,5	—	33,0 to 33,4	—
K	23,8 to 24,7	—	29,2 to 29,5	—	31,5 to 31,7	—	32,9 to 35,0	—
L	12,0 to 12,2	±0,2	n.a.	n.a.	0	n.a.	n.a.	n.a.
M	24,0 to 24,2	±0,2	28,4 to 28,7	±0,2	33,3 to 33,5	±0,2	39,6 to 39,8	±0,2
N	0,0 to 1,0	n.a.	0,0 to |1,0|	n.a.	0 to |1,0|	n.a.	0,0 to |1,0|	n.a.
O	15,5 to 16,2	—	18,2 to 19,0	—	22,6 to 23,1	—	32,6 to 33,7	—

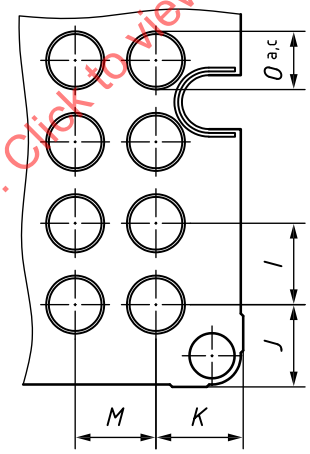
NOTE Measure of *N* for empty nests delivered to the syringe manufacturers typically show nest deflections of a maximum of 2,5 mm. The range 0,0 to |1,0| mm accounts for nests filled with subassembled syringes.



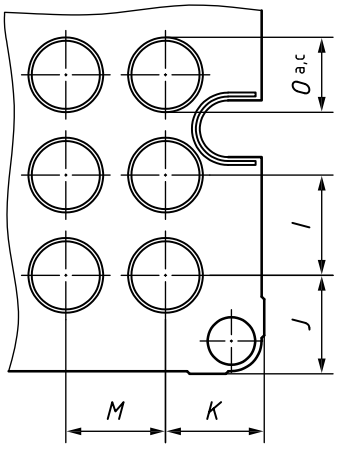
a) 64 cavity nest for compatible barrel sizes 5 ml



b) 20 cavity nest for compatible barrel sizes 50 ml



c) 42 cavity nest for compatible barrel sizes 10 ml



d) 40 cavity nest for compatible barrel sizes 20 ml

Key

1 customized ribbing to reinforce the nest stability against deflection

2 restricted area for suction cups

a 64 x Ø *O*, 20 x Ø *O*, 42 x Ø *O*, and 30 x Ø *O* respectively (see Table A.3).

b Maximum deflection (can occur in both directions).

c Cavities are equipped with inside chamfers on both ends to support de- and re-nesting process.

NOTE Potentially, there are more restricted areas for suction cups than indicated in the figure.

Figure A.3 — Guidance on design of a 64, 42, 30, and 20 cavity nest

Annex B
(informative)

Design of tubs

This annex intends to harmonize tubs for sterilized subassembled syringes ready for filling to facilitate the handling and processing of prefilled syringes. For this purpose, Table B.1 includes:

— the recommended range of nominal dimensions of tubs representing the current status of harmonization;

— the corresponding nominal dimensions that are offered for further harmonization;

— the recommended tolerance reflecting manufacturing tolerances for critical attributes.

The dimensions may be measured by means of tactile or optical measurement systems.

Figure B.1 represents an example of the design of tubs.

Customers and manufacturers should agree upon the dimensions and tolerances of the finished product as delivered.

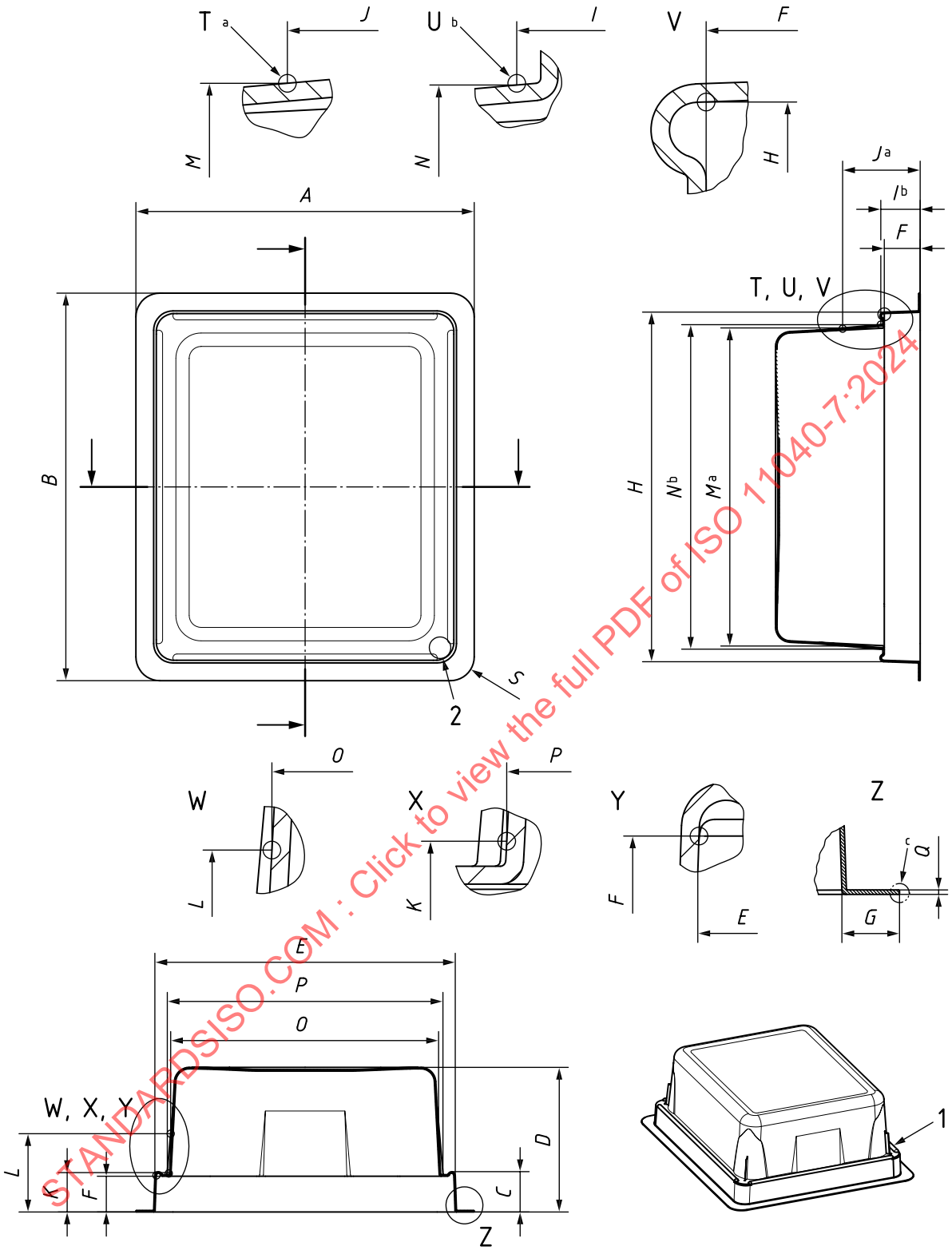
Table B.1 — Guidance on dimensions of a commonly called 3” tub (see Figure B.1)

Dimensions in millimetres

Position	Recommended range of nominal dimensions	Nominal dimension	Recommended tolerance	Remarks
A	226,9 to 227,4	227	—	—
B	259,5 to 260,0	260	—	—
C	26,2 to 27,2	27	—	—
D	96,9 to 97,8	97,5	±1,0	—
E	198,9 to 201,3	201,3	—	inside
F	23,8 to 24,2	24	—	inside
G	12,3 to 13,8	12,7	—	—
H	231,3 to 233,3	233,3	—	inside
I = *K*	26,4[a]	—	—	measuring point angle
L = *J*	52,5 [a]	—	—	measuring point angle
M	213,3 to 214,0	—	—	measuring point angle
N	216,1 to 218,5	218	—	measuring point angle
O	179,2 to 181,1	179,9	—	measuring point angle
P	181,9 to 185,0	183	—	measuring point angle
Q	0,85 to 1,20	—	—	Rim thickness
S	R 16	—	±0,5	—

[a] As this is a measuring height, a range does not apply.

NOTE Other tubs commonly on the market are, for example, 4”, 6”, and 6 3/4” tubs. These tubs are, at this stage, not defined.



Key

1 customized stack ribs

2 flat areas for suction cups

[a] *J* and *M* checked on reinforced area.

[b] *I* and *N* checked on reinforced area.

[c] Rounded edge recommended on both sides to avoid loss of integrity of various packaging layers.

NOTE The bottom of the tub can be recessed or flat.

Figure B.1 — Guidance on the design of a commonly called 3” tub

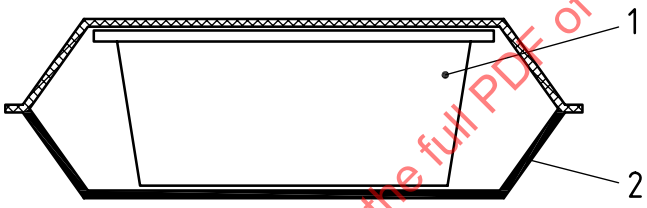
Annex C
(informative)

Schematic illustrations of examples of protective bag configurations

The following schematic illustrations represent examples for protective bag configurations. The long dimension of the tub should be aligned with the long dimension of the protective bag.

Typical configurations are illustrated in Figure C.1 showing a bag with top web entirely made from a porous material and Figure C.2 showing a bag with a porous window, typically referred to as a header bag. The orientation of the porous areas can have an impact on sterilization efficiency, the configuration in Figure C.3 is not recommended as it reduces the permeability for sterilization gases versus the configuration in Figure C.1 and Figure C.2. For double bags an orientation as illustrated in Figure C.4 or Figure C.6 with windows located on top of each other is preferable versus a configuration in Figure C.5 to allow for sufficient permeability for sterilization gases and air.

NOTE For guidance of different packaging types, see ISO 11607-1:2019, Annex A. For the dimensions of tubs and protective bags, see Annexes B and Annex D.

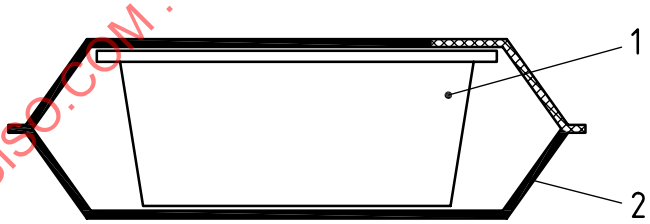


Key

1 tub

2 protective bag

Figure C.1 — Example 1 — Bag with top web porous material

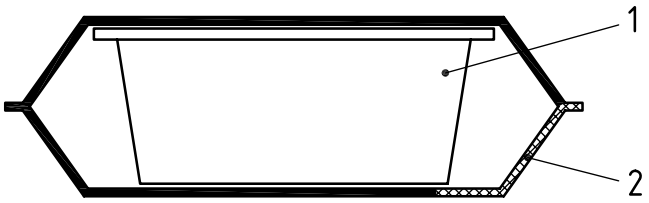


Key

1 tub

2 protective bag

Figure C.2 — Example 2 — Header bag upwards

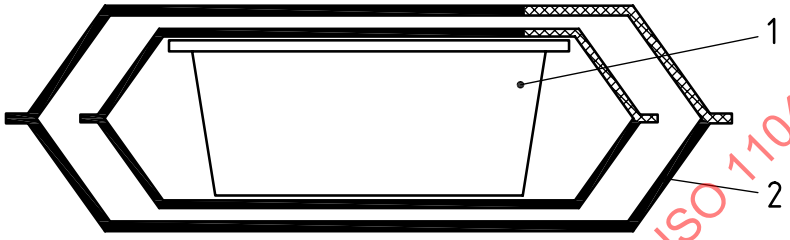


Key

1 tub

2 protective bag

Figure C.3 — Example 3 — Header bag downwards

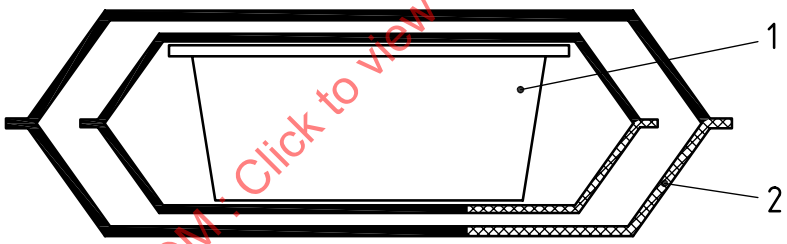


Key

1 tub

2 protective bag

Figure C.4 — Example 4 — Double bag upwards

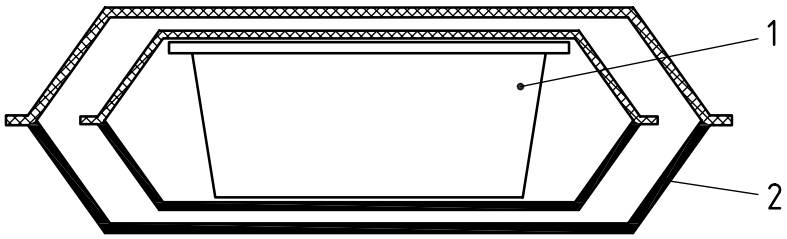


Key

1 tub

2 protective bag

Figure C.5 — Example 5 — Double bag downwards



Key

1 tub

2 protective bag

Figure C.6 — Example 6 — Double bag with top web porous material

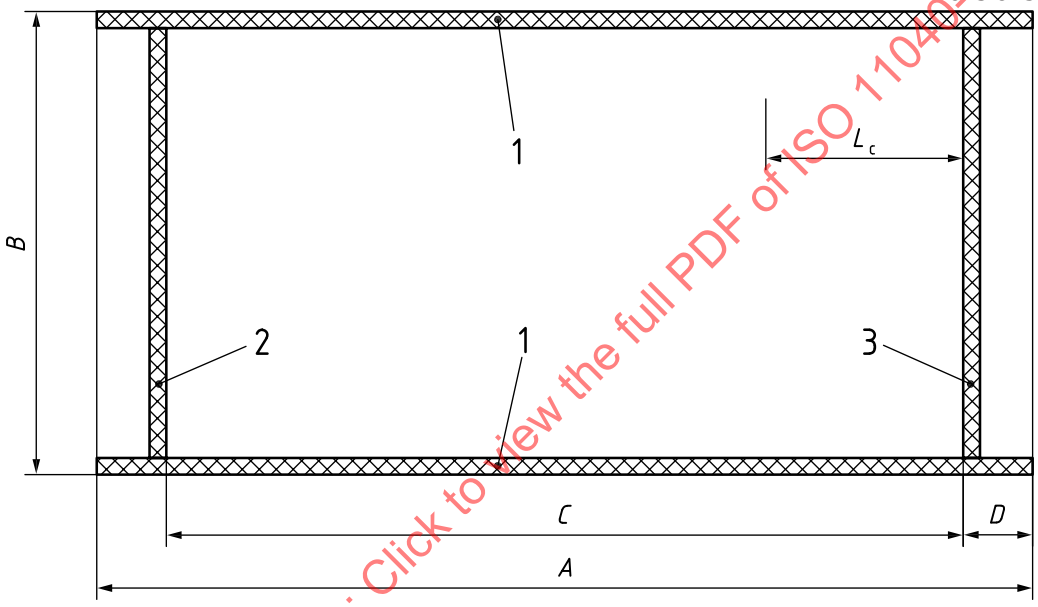
Annex D
(informative)

Design and dimensions of the protective bag for 3” and 4” tubs

D.1 Design

There are many designs of protective bags and Figure D.1 and Figure D.2 only represent examples of commonly used protective bags. Dimensions are subject to agreement between the manufacturer and the customer.

Dimensions in millimetres



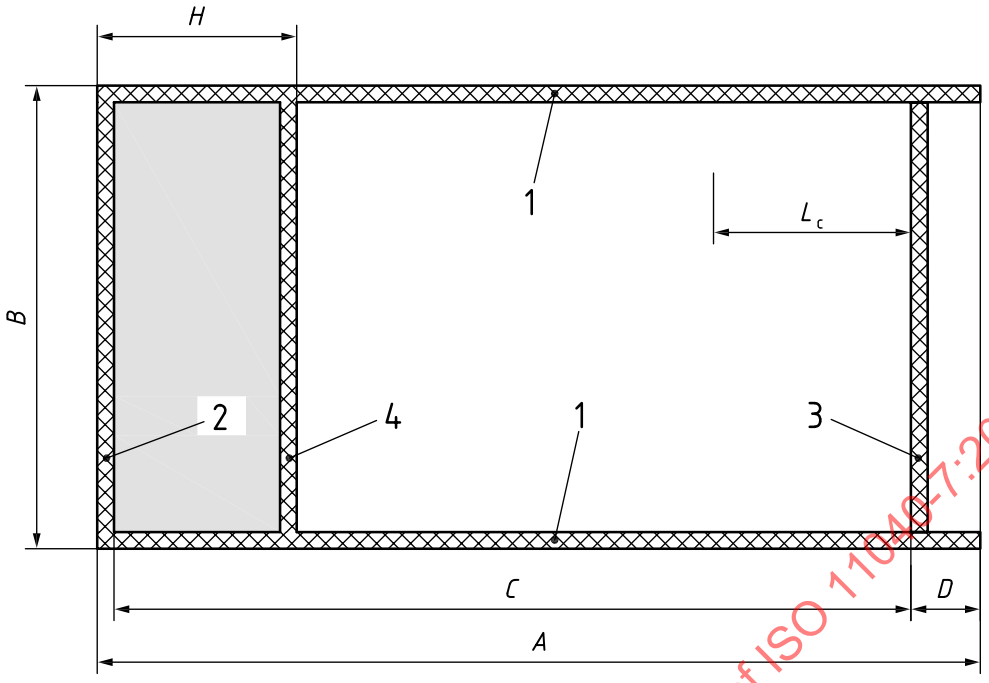
Key

L_c	length of cutting area
A	overall length
B	overall width
C	distance between seals 2 and 3
D	max. distance of welding seam from end of the bag
1, 2, 3	seal 1, seal 2, seal 3

NOTE Seal 3 is typically made after inserting the tub.

Figure D.1 — Illustration of an example of a bag with top web porous material

Dimensions in millimetres



Key

L_c	length of cutting area
A	overall length
B	overall width of the bag
C	distance between end of seal 2 and beginning of seal 3
D	max. distance of welding seam from end of the bag
H	length of porous material window
1, 2, 3, 4	seal 1, seal 2, seal 3, seal 4

NOTE Seal 3 is typically made after inserting the tub.

Figure D.2 — Illustration of an example of a header bag with window

Table D.1 — Guidance on dimensions

Dimensions in millimetres

Position	Range of nominal dimensions for bags and header bags[a]		
	Market range	Recommended dimensions for 3” tubs	Recommended dimensions for 4” tubs
A	435 to 515	455 to 465	480 to 510
B	380 to 410	380 to 390	430 to 440
D	≤40	≤40	≤40

[a] These range of values refer to the finished product as delivered to the customer. There can be a combination of the recommended bag sizes used as inner and outer bag in a double bag configuration.

NOTE 1 inch = 25,4 mm.