SLOVENSKI STANDARD
oSIST prEN ISO 22916:2022

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Mikrofluidne naprave - Zahteve za interoperabilnost dimenzij, priključkov in začetne razvrstitve naprav (ISO 22916:2022)

Microfluidic devices - Interoperability requirements for dimensions, connections and initial device classification (ISO 22916:2022)

Mikrofluidikgeräte - Interoperabilitätsanforderungen für Abmessungen, Anschlüsse und anfängliche Geräteklassifizierung (ISO 22916:2022)

Dispositifs microfluidiques - Exigences d’interopérabilité concernant les dimensions, les connexions et la classification initiale des dispositifs (ISO 22916:2022)

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Microfluidic devices — Interoperability requirements for dimensions, connections and initial device classification

Dispositifs microfluidiques — Exigences d'interopérabilité concernant les dimensions, les connexions et la classification initiale des dispositifs

Reference number
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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 documents 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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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 48, *Laboratory equipment*.

This first edition of ISO 22916 cancels and replaces IWA 23:2016, which has been technically revised.

The main changes are as follows:

— the content of IWA 23 was transferred into a standard for the first time;

— the terms and definitions have been removed in the present document and it refers mainly to ISO 10991;

— the rationale behind technical decisions in IWA 23 have been removed from the present document;

— the geometrical pitch dimensions are included in Clause 4;

— the device classification is included in Clause 9;

— further information have been introduced in the present document.

NOTE IWA 23 initiated the standardization effort in microfluidics and presented mainly the terms and definitions, the geometrical pitch rationale and dimensions and the device classification rationale and proposal.

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

This document was developed in response to microfluidics community demand for minimum specifications for interoperability of microfluidics components, since most of the microfluidics products are produced internally with custom dimensions and characteristics.

Microfluidics based diagnostics have been shown over the years to be viable alternatives to conventional macroscale analysis systems, and in some applications provide analytical capabilities which are not possible using macroscale systems. Hence, exploitation of microfluidics will play an important role for next generation of medical devices. However, there are many (potential) applications for microfluidics, and also many technologies and materials being used. This diversity is a problem when it comes to combining microfluidic components. Researchers do not want to spend much time on side issues like correct connection of tooling; they also want to use chips from different suppliers without needing to change their whole experimental setup; and they want their developed products to go as smoothly as possible into production. Providers of analytical services do not want their limited laboratory space cluttered with a multitude of incompatible instruments. Chemical engineers want easy interconnection between pumps, sensors and reactors, and finally, operational managers want a second source for their products. In short interoperability and therefore standardizing the interfaces between them is important.

Another essential requirement for interoperability is standardization of testing. Testing may be partly very application specific, but there are also tests that are to be used cross application, cross technology and cross material; for instance leakage test, burst pressure tests and flow throughput tests. The test protocol is developed considering the material of the chips, the temperature and pressure range of operation. From studies of the products on the market, a number of application classes with specific temperature and pressure ranges have been defined, that will provide the boundary conditions for the tests to be developed. Ultimately, these tests will lead to quicker access to the market.

Microfluidic devices — Interoperability requirements for dimensions, connections and initial device classification

1 Scope

This document specifies requirements for the seamless integration with other microfluidic components and systems to facilitate the process of designing new microfluidic devices (e.g. microfluidic chips, sensors, actuators, connectors).

This document is applicable to devices in the field of “microfluidics” needing microfluidic interconnections.

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 10991, *Micro process engineering — Vocabulary*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 10991 apply.

ISO and IEC maintain terminological 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/

4 General dimension tolerances

Table 1 and Table 2 present the recommended general dimension tolerances regarding port pitches, chip thicknesses and port dimensions respectively for top connections and for side connections. In the tables and in the document *n* is an integer ≥1.

Table 1 — Key parameters for top connections

Dimensions in millimetres

Parameters	Nominal value	Minimal value	Maximal value	Tolerance
Reference point	(0; 0)			
Distance of the first hole from the reference point (except for microplate compatibility)	(3; 3)			±0,15
Minimal distance of any hole from any side of the chip		3		
Port pitch	*n* × 1,5			±0,10
Distance between rows of ports	*n* × 1,5			±0,10
Port diameter for 1,5 mm grid		0,4	0,7	
Port diameter for 3 mm grid		0,4	2,0	
Port diameter for 4,5 mm grid		0,4	3,5	
Tight tolerance of outer chip dimension (desired)				±0,05
Lower tolerance of outer chip dimension				±0,15

Table 2 — Key parameters for side connections

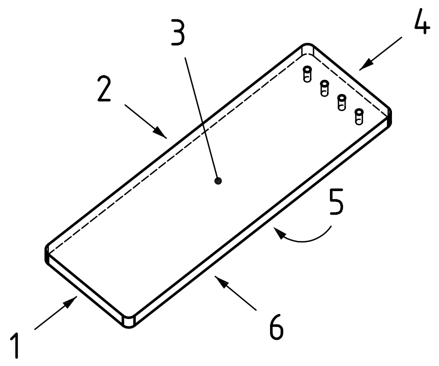
Dimensions in millimetres

Parameters	Nominal value	Minimal value	Maximal value	Tolerance
Reference point	(0; 0; 0)			
Distance of the first hole from the *Z* axis	3			±0,15
Port pitch	*n* × 1,5			±0,10
Total chip thickness	0,8	0,7	0,9	±0,10
	1	0,9	1,1	±0,10
	1,1	1,0	1,2	±0,10
	1,4	1,3	1,5	±0,10
	1,8	1,65	1,95	±0,15
	2	1,80	2,20	±0,20
	4	3,60	4,40	±0,20
Tight tolerance of outer chip dimension (desired)	*n* × 15	15	30	±0,05
Lower tolerance of outer chip dimension				±0,15

5 Chip reference point and topology

5.1 Chip topology

The chip is a flat microfluidic device. Figure 1 describes the names for each side of the chip.



Key

1 lower side
2 left side
3 top
4 upper side
5 bottom
6 right side

Figure 1 — Schematics showing top, bottom and sides of a chip

5.2 Naming of the chip

The name of a rectangular (or square) chip shall contain information about the length and the width, defining an X-axis and a Y-axis. The X-axis shall be the direction with most of the fluidic connections. Then, the name of the chip shall contain $X \times Y$ with the correct values.

EXAMPLE For a component of 15 mm by 30 mm with fluidic connections along the short length, the name of the chip contains at least 15 × 30. For example, “rectangular chip 15 × 30”.

5.3 Reference point

The reference point is the intersection of the X-axis and the Y-axis. With the X-axis pointing from left to right, the reference point is at the top left of the chip as described in Figure 2.