

# SLOVENSKI STANDARD SIST EN 415-3:2021

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Safety of packaging machines - Part 3: Form, fill and seal machines; fill and seal machines

Sicherheit von Verpackungsmaschinen - Teil & Form-, Füll- und Verschließmaschinen; Füll- und Verschließmaschinen (standards.iteh.ai)

Sécurité des machines d'emballage - <u>Partie 3:543421</u> et sceller ; machines d'emballage à remplir et sceller <sub>67389-94bd-47ea-9c31-</sub> 28ada63bf487/sist-en-415-3-2021

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55.200 Pakirni stroji

Packaging machinery

SIST EN 415-3:2021

en,fr,de



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#### SIST EN 415-3:2021

# **EUROPEAN STANDARD** NORME EUROPÉENNE **EUROPÄISCHE NORM**

# EN 415-3

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ICS 55.200

Supersedes EN 415-3:1999+A1:2009

**English Version** 

# Safety of packaging machines - Part 3: Form, fill and seal machines: fill and seal machines

Sécurité des machines d'emballage - Partie 3 : Machines d'emballage à former, remplir et sceller ; machines d'emballage à remplir et sceller

Sicherheit von Verpackungsmaschinen - Teil 3: Form-, Füll- und Verschließmaschinen; Füll- und Verschließmaschinen

This European Standard was approved by CEN on 6 September 2021.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions. (standards.iteh.ai)

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EUROPEAN COMMITTEE FOR STANDARDIZATION COMITÉ EUROPÉEN DE NORMALISATION EUROPÄISCHES KOMITEE FÜR NORMUNG

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## Contents

European foreword		3
Introduction		
1	Scope	6
2	Normative references	7
3	Terms and definitions	9
3.1	Definitions of terms	9
3.2	Definitions of machines covered by this document	13
3.3	Definitions of machines which have similar hazards to those machines covered by	
	this document	20
4	Safety requirements	24
4.1	General requirements	24
4.2	Safety requirements for a flow-wrapping machine	32
4.3	Safety requirements for a vertical form, fill and seal machine	39
4.4	Safety requirements for a horizontal sachet form, fill and seal machine	42
4.5	Safety requirements for a thermoform, fill and seal machine	44
4.6	Safety requirements for a tubular bag form, fill and seal machine	51
4.7	Safety requirements for a mandrel form, fill and seal machine	53
4.8	Safety requirements for a pre-made bag fill and close machine	57
4.9	Safety requirements for a cup of tub fill and seal machine	59
4.10	Safety requirements for a sack fill and sear machine.	62
4.11	Safety requirements for a volumetric with filler 1-415-3-2021	07
4.13	Safety requirements for a nett weigher	07
4.14	Safety requirements for a multi-head weigher	73
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5	Verification of safety requirements	75
5.1	General	75
5.Z	Visual Inspections with the machine stopped	75
5.5 5.4	Visual inspections with the machine running	70
55	Measurements or tests with the machine running	70
5.6	Verification procedures	
6		00
0	Information	08
0.1 6 2	General	00 80
63	Warning of residual risks	00 81
6.4	Instructions	81
Annex	A (informative) List of significant hazards	87
Annex B (normative) Noise test code		
Annex	EZA (informative) Relationship between this European Standard and the Essential Requirements of EU Directive 2006/42/EC aimed to be covered	123
Bibliography		127

## **European foreword**

This document (EN 415-3:2021) has been prepared by Technical Committee CEN/TC 146 "Packaging machines – Safety", the secretariat of which is held by UNI.

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 April 2022, and conflicting national standards shall be withdrawn at the latest by April 2022.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document has been prepared under a Standardization Request given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative Annex ZA, which is an integral part of this document.

This document supersedes EN 415-3:1999+A1:2009.

The following significant changes have been made:

- Scope now includes fill and seal machines and multi-head weighers;
- Cartoning machines have been removed from the scope;
- Safety requirements have been rewritten so they are in line with EN 415-10:2014; https://standards.iteh.ai/catalog/standards/sist/5cef7389-94bd-47ea-9c31-
- Normative references have been changed to reflect the many changes that have been made to B1 and B2 standards.
- EN 415, Safety of packaging machines consists of the following parts:
- Part 1: Terminology and classification of packaging machines and associated equipment;
- Part 2: Pre-formed rigid container packaging machines;
- Part 4: Palletizers and depalletizers;
- Part 5: Wrapping machines;
- Part 6: Pallet wrapping machines;
- Part 7: Cartoning and case-packing machines;
- Part 8: Strapping machines;
- Part 9: Noise measurement methods for packaging machines, packaging lines and auxiliary equipment, grade of accuracy 2 and 3;
- Part 10: General requirements.

Any feedback and questions on this document should be directed to the users' national standards body. A complete listing of these bodies can be found on the CEN website.

According to the CEN-CENELEC Internal Regulations, the national standards organisations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

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## Introduction

Form, fill and seal machines and fill and seal machines are used extensively in Europe, in an increasingly wide range of industries. They contain many hazards and have the potential to cause serious injury.

This document is a type-C standard as stated in EN ISO 12100.

This document is of relevance, in particular, for the following stakeholder groups representing the market players with regard to machinery safety:

- machine manufacturers (small, medium and large enterprises);
- health and safety bodies (regulators, accident prevention organizations, market surveillance, etc.).

Others can be affected by the level of machinery safety achieved with the means of the document by the above-mentioned stakeholder groups:

- machine users/employers (small, medium and large enterprises);
- machine users/employees (e.g. trade unions, organizations for people with special needs);
- service providers, e.g. for maintenance (small, medium and large enterprises);

The above-mentioned stakeholder groups have been given the possibility to participate at the drafting process of this document. The machinery concerned and the extent to which hazards, hazardous situations or hazardous events are covered are indicated in the Scope of this document.

When requirements of this type-**C**standard are different from those which are stated in type-A or type-B standards, the requirements of this type-C standard take precedence over the requirements of the other standards for machines that have been <u>designed</u> and built according to the requirements of this type-C standard. <u>https://standards.itch.ai/catalog/standards/sist/5cef7389-94bd-47ea-9c31-</u>

28ada63bf487/sist-en-415-3-2021

#### 1 Scope

This document establishes safety requirements for the main types of form, fill and seal machines, fill and seal machines and the filling machines which are frequently fitted to these machines.

Form fill and seal machines within the scope of this document are:

- flow wrapping machine;
- vertical form, fill and seal machine;
- horizontal sachet form, fill and seal machine;
- thermoform, fill and seal machine;
- tubular bag form, fill and seal machine;
- mandrel form, fill and seal machine.

Fill and seal machines within the scope of this document are:

- pre-made bag, erect, fill and seal machine;
- cup or tub fill and seal machine;
- sack fill and seal machine iTeh STANDARD PREVIEW

Filling machines commonly fitted to form, fill and seal machines and fill and seal machines within the scope of this document are:

auger filler;

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- volumetric cup filler;
- nett weigher;
- multi-head weigher.

Other types of form, fill and seal machine which are described in 3.3 have similar hazards to these machines and Clause 4 indicates which clauses of this document are applicable to these machines.

This document covers the safety requirements for machine design, construction and all phases of life of the machines including installation, commissioning, operation, adjustment, maintenance and cleaning.

This document applies to machines manufactured after the date of publication of this document.

This document does not apply to:

- blow mould fill and seal machines;
- bulk container fill and seal machines;
- cartoning machines;
- food depositors, including volumetric piston depositors in the scope of EN 15180;
- thermoforming machines in the scope of EN 12409.

This document does not consider:

- hazards due to the products packed in these machines, but does consider the hazards caused by dusts, modified atmosphere gases, and flammable products;
- hazards resulting from the operation of the machines in a potentially explosive atmosphere.

#### 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.

EN 415-1:2014, Safety of packaging machines — Part 1: Terminology and classification of packaging machines and associated equipment

EN 415-9:2009, Safety of packaging machines — Part 9: Noise measurement methods for packaging machines, packaging lines and associated equipment, grade of accuracy 2 and 3

EN 415-10:2014, Safety of packaging machines — Part 10: General Requirements

EN 618:2002+A1:2010, Continuous handling equipment and systems — Safety and EMC requirements for equipment for mechanical handling of bulk materials except fixed belt conveyors

EN 620:2002+A1:2010, Continuous handling equipment and systems - Safety and EMC requirements for fixed belt conveyors for bulk materials (standards.iteh.ai)

EN 1005-2:2003+A1:2008, Safety of machinery — Human physical performance — Part 2: Manual handling of machinery and component parts of machinery

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EN 1127-1:2019, Explosive atmospheres 3 Explosion prevention and protection — Part 1: Basic concepts and methodology

EN 1672-2:2020, Food processing machinery — Basic concepts — Part 2: Hygiene and cleanability requirements

EN 15180:2014, Food processing machinery — Food depositors — Safety and hygiene requirements

EN 60079-14:2014, *Explosive atmospheres* — Part 14: Electrical installations design, selection and erection (IEC 60079-14:2013)

EN 60204-1:2018, Safety of machinery — Electrical equipment of machines — Part 1: General requirements (IEC 60204-1:2018)

EN 60825-4:2006, Safety of laser products — Part 4: Laser guards

EN 61496-1:2013, Safety of machinery — Electro-sensitive protective equipment — Part 1: General requirements and tests

EN 61496-2:2013, Safety of machinery — Electro-sensitive protective equipment — Part 2: Particular requirements for equipment using active opto-electronic protective devices (AOPDs) (IEC 61496-2:2013)

EN IEC 61496-3:2019, Safety of machinery — Electro-sensitive protective equipment — Part 3: Particular requirements for active opto-electronic protective devices responsive to diffuse Reflection (AOPDDR) (IEC 61496-3:2018)

EN ISO 4413:2010, Hydraulic fluid power — General rules and safety requirements for systems and their components (ISO 4413:2010)

EN ISO 4414:2010, Pneumatic fluid power — General rules and safety requirements for systems and their components (ISO 4414:2010)

EN ISO 7010:2020, Graphical symbols — Safety colours and safety signs — Registered safety signs (ISO 7010:2019, Corrected version 2020-06)

EN ISO 11688-1:2009, Acoustics — Recommended practice for the design of low-noise machinery and equipment — Part 1: Planning (ISO/TR 11688-1:1995)

EN ISO 12100:2010, Safety of machinery — General principles for design — Risk assessment and risk reduction (ISO 12100:2010)

EN ISO 13732-1:2008, Ergonomics of the thermal environment — Methods for the assessment of human responses to contact with surfaces — Part 1: Hot surfaces (ISO 13732-1:2006)

EN ISO 13849-1:2015, Safety of machinery — Safety-related parts of control systems — Part 1: General principles for design (ISO 13849-1:2015)

EN ISO 13850:2015, Safety of machinery — Emergency stop function — Principles for design (ISO 13850:2015)

EN ISO 13851:2019, Safety of machinery Two-hand control devices, principles for design and selection. (ISO 13851:2019) (standards.iteh.ai)

EN ISO 13854:2019, Safety of machinery — Minimum gaps to avoid crushing of parts of the human body (ISO 13854:2017) <u>SIST EN 415-3:2021</u>

https://standards.iteh.ai/catalog/standards/sist/5cef7389-94bd-47ea-9c31-

EN ISO 13855:2010, Safety of machinery —<sup>28</sup>Positioning of safeguards with respect to the approach speeds of parts of the human body (ISO 13855:2010)

EN ISO 13856-2:2013, Safety of machinery — Pressure-sensitive protective devices — Part 2: General principles for design and testing of pressure-sensitive edges and pressure-sensitive bars (ISO 13856-2:2013)

EN ISO 13857:2019, Safety of machinery — Safety distances to prevent hazard zones being reached by upper and lower limbs (ISO 13857:2019)

EN ISO 14119:2013, Safety of machinery — Interlocking devices associated with guards — Principles for design and selection (ISO 14119:2013)

EN ISO 14120:2015, Safety of machinery — Guards — General requirements for the design and construction of fixed and movable guards (ISO 14120:2015)

EN ISO 14122-2:2016, Safety of machinery — Permanent means of access to machinery — Part 2: Working platforms and walkways (ISO 14122-2:2016)

EN ISO 14122-3:2016, Safety of machinery — Permanent means of access to machinery — Part 3: Stairs, stepladders and guard-rails (ISO 14122-3:2016)

EN ISO 14122-4:2016, Safety of machinery — Permanent means of access to machinery — Part 4: Fixed ladders (ISO 14122-4:2016)

EN ISO 14123-1:2015, Safety of machinery — Reduction of risks to health resulting from hazardous substances emitted by machinery — Part 1: Principles and specifications for machinery manufacturers (ISO 14123-1:2015)

EN ISO 14123-2:2015, Safety of machinery — Reduction of risks to health resulting from hazardous substances emitted by machinery — Part 2: Methodology leading to verification procedures (ISO 14123-2:2015)

EN ISO 14159:2008, Safety of machinery — Hygiene requirements for the design of machinery (ISO 14159:2002)

ISO 3864-1:2011, Graphical symbols — Safety colours and safety signs — Part 1: Design principles for safety signs and safety markings

ISO 3864-2:2016, Graphical symbols — Safety colours and safety signs — Part 2: Design principles for product safety labels

ISO 3864-3:2012, Graphical symbols — Safety colours and safety signs — Part 3: Design principles for graphical symbols for use in safety signs

#### 3 Terms and definitions

For the purposes of this document, the terms and definitions given in EN ISO 12100:2010, EN 415-1:2014, EN 415-10:2014 and the following apply. REVIEW

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

IEC Electropedia: available at <a href="https://www.electropedia.org/">https://www.electropedia.org/</a>

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- ISO Online browsing platform: available at https://wwww.isolorg/obpc31-

28ada63bf487/sist-en-415-3-2021

#### **3.1 Definitions of terms**

#### 3.1.1

#### automatically adjustable guard

movable guard attached to a moveable machine element (e.g. moving side of a pre-made bag magazine) and a fixed machine element (e.g. machine frame) which moves automatically when the moveable element is adjusted

Note 1 to entry: An automatically adjustable guard does not comply with this definition unless it has been dimensioned and positioned using relevant tables of EN ISO 13857:2019.

#### 3.1.2

#### bag

flat or gusseted flexible container longitudinally seamed and closed at one or both ends made from paper, plastic film, foil, laminate, etc.

Note 1 to entry: Bags produced on form, fill and seal machines will typically have a seal at both ends and a longitudinal seal running down the centre of the rear face of the bag.

#### 3.1.3

#### change parts

machine parts designed to handle a specific product, packaging material or pack size that need to be changed when the machine is set up to handle a different product, packaging material or pack size

#### 3.1.4

#### change part guard

fixed or interlocking guard which has been made to suit one product or pack size and must be changed every time the product or pack size is changed

Note 1 to entry: A change part guard does not comply with this definition unless it has been dimensioned and positioned using relevant tables of EN ISO 13857:2019.

3.1.5

cup

tub

thin walled tapered container

#### 3.1.6

#### deformable material

material which can be formed by the application of pressure alone

#### 3.1.7

food depositor

machine that dispenses a food product in a predetermined volume or shape

#### 3.1.8

film reel

iTeh STANDARD PREVIEW packaging material reel continuous sheet of paper, carton board, plastic film, metal foil or flexible laminate wound on a cylindrical (standards.iteh.ai) core

#### 3.1.9

SIST EN 415-3:2021 film web https://standards.iteh.ai/catalog/standards/sist/5cef7389-94bd-47ea-9c31continuous sheet of paper, plastic film, metal foil of laminate 15-3-2021

#### 3.1.10

#### fixed guard

guard affixed in such a manner (for example, by screws, nuts, and welding) that it can only be opened or removed by the use of tools or by destruction of the means by which the guard is affixed

A fixed guard does not comply with this definition unless it complies with subclause 4.1.2.2 of Note 1 to entry: this document.

#### 3.1.11

#### hot melt adhesive

adhesive that is solid at room temperature and which is melted and applied at elevated temperature

#### 3.1.12

#### interlocking guard

guard associated with an interlocking device so that, together with the control system of the machine, the following functions are performed:

- the hazardous machine functions "covered" by the guard cannot operate until the guard is closed;
- if the guard is opened while hazardous machine functions are operating, a stop command is given;
- when the guard is closed, the hazardous machine functions "covered" by the guard can operate (the closure of the guard does not, by itself, start the hazardous machine functions)

Note 1 to entry: An interlocking guard does not comply with this definition unless it complies with subclause 4.1.2.2 of this document.

#### 3.1.13

#### longitudinal seal

seal made on a package in line with the direction of material travel in the machine

#### 3.1.14

#### magazine

mechanical assembly designed to hold stacks of cartons, carton blanks, pre-made bags, pre-made sacks, leaflets, labels, lids or stackable containers

#### 3.1.15

#### mandrel

mechanical assembly around which a flexible package or carton is formed

#### 3.1.16

#### manually adjustable guard

adjustable guard where the adjustment is made manually and the adjustment remains fixed during a particular operation

Note 1 to entry: A manually adjustable guard does not comply with this definition unless it complies with subclause 4.1.2.2 of this document.

#### 3.1.17

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#### modified atmosphere

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atmosphere where the normal atmosphere within a package is completely or partially replaced by one or more selected gases <u>SIST EN 415-3:2021</u>

Note 1 to entry: Usually the objective is to extend shelf or storage life of the packaged products.

#### 3.1.18

#### pack

#### package

assembly of product and packaging materials produced by a packaging machine

#### 3.1.19

#### packaging material

material used to make a package

EXAMPLEs Film laminate, carton board, paper.

#### 3.1.20

#### packaging material transport mechanism

mechanical assembly which transports packaging material through the packaging machine

#### 3.1.21

#### pre-made bag

pre-formed flat or gusseted flexible package longitudinally seamed and closed at one end made from paper, plastic film, foil, laminate or a woven material

#### 3.1.22

#### pre-made sack

pre-formed flat or gusseted sack longitudinally seamed and closed at one or both ends made from paper, plastic film, laminate, or a woven material

#### 3.1.23

#### product

substance, article pack or package that is handled in the packaging machine

#### 3.1.24

#### reclosing feature applicator

mechanism which applies a zip or self-adhesive packaging component to a package on a packaging machine

#### 3.1.25

#### sachet

flat package which when formed from two webs of flexible material is sealed on four sides and when formed from one web is sealed on three or four sides

#### 3.1.26

3.1.27

sack placer

mechanism which places an empty pre-made sack onto a filling spout

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#### sack transfer mechanism

## mechanism which takes empty sacks from a sack magazine and transfers them to a sack placer

#### 3.1.28 soil

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any unwanted matter, including product residues, micro-organisms, residual detergent or disinfecting agents

#### 3.1.29

transverse seal

seal made on a package at right angles to the direction of material travel in the machine

#### 3.1.30

#### trip guard

interlocking guard which is designed to move easily when touched by someone and which stops the machine before a hazard zone can be reached

#### 3.1.31

#### tubular bag

flexible package closed at both ends and made from a flat film tube

### 3.2 Definitions of machines covered by this document

#### 3.2.1 Form, fill and seal machines

#### 3.2.1.1

#### flow-wrapping machine

horizontally operating form, fill and seal machine with material reel mounted above the operating level, the product loaded horizontally and a longitudinal seal formed below the pack

