

## **Supplementary information**

## Approvals and certificates





Document ID: 36200



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### 1 About this document

This supplementary instructions manual gives you an overview of the different national, international as well as industry-specific approvals, certificates and conformities available for VEGA sensors. Claim for completeness is not enforced due to the complexity of the matter.

You will find the availability for the respective sensors on our homepage <a href="www.vega.com">www.vega.com</a> under "Downloads", "Approvals".

You can find additional information on the Internet pages specified in the document.

Also take note of the operating instructions manuals, approvals, safety instructions and any other possible documents for the instrument. The relevant documents are available in the download section on our homepage.



### 2 CE conformity

### 2.1 Overview



The CE marking (either from the French Communauté Européenne = "European Community" or Conformité Européenne as much as "Conformity with EU directives") is a mark according to EU law for certain products in relation to product safety. With the CE mark, the manufacturer confirms that the product corresponds to the applicable European directives. The CE mark allows no conclusions if the product was tested by independent authorities on the compliance with these directives. If there is a four digit figure after the CE mark, this means that a notified body is involved in the conformity assessment procedure. The CE mark is no seal of quality (quality mark).

### 2.2 Development, function

#### Objective

The CE marking was primarily created to ensure safe products to the end user in the free movement of goods within the European Economic Area (EEA) and the European Community (EC). The CE marking is often called "passport" for the Single European Market. The EC directive according to Article 95 EC Treaty (so called Single European Market directives) determines safety and health requirements for a number of products as min. requirements which must not be underrun. A product must only be put into circulation and set up if it corresponds to all applicable EC regulations and if a conformity assessment prodecure was carried out according to the applicable EC directives. Within the new concept for product regulation and the total concept of conformity assessment, adjustment factors were created which should be used for technical harmonization of the Single European Market.

#### Commitment

The manufacturer confirms with the CE marking the conformity of the product with the applicable EC directive and the compliance with the stipulated "general requirements". The manufacturer of the product (for manufacturers outside the EU, an authorized person located in the EU is required) is normally responsible for the marking. As far as the manufacturer has not attended his duty outside the EU, this duty is passed on to his representative in the EU or the importer or at least the distributor (colloquially the "Seller").

#### **Features**

Products for which due to their kind or character, one of the EC directives can be applied, must be provided with the CE marking before they are put into circulation or set up. Manufacturers of a technical product check on their own risk which EC directives they have to apply during production. The product must only be put into circulation or set up if it complies with all applicable directive and as far as the conformity assessment was carried out according to all applicable directives. The manufacturer creates an EC conformity declaration and provides a CE marking on the product. If required, a



notified body must be engaged for conformity assessment. Apart from te CE marking, no other signs or quality seals are permitted which can question the declaration of "CE". The CE marking confirms the complete compliance with the "General (safety) requirements" which are explicitly stipulated in the EC directives. Exceptions from these directive only exist if special directives stipulate different regulations.

#### 2.3 Scope

The CE marking is a prerequisite for putting products into circulation (or setting up) for the first time for which the CE marking is required according to the following EC directives, i.e. in all member states of the European Economic Area (EEA). The EEA comprises die EU member states, except Switzerland. The CE marking is not required for putting products into circulation in Switzerland. There are many special conformity marking, the CE marking according to the EU directives, however, is accepted.

http://ec.europa.eu



### 3 Explosion protection Europe

#### 3.1 Overview

CENELEC

Within the European Community, CENELEC (European Committee for Electrotechnical Standardization) develops amongst others harmonized regulations for the construction and test of electrical instruments for hazardous areas.

Members of CENELEC are the national electrotechnical standardisation committees of most European countries.

#### www.cenelec.eu

## Explosion protection (Ex)



When handling substances that can react which oxygen, an explosion danger must always be expected if there is a combustible substance with a certain partial pressure in a room volume.

In explosion-endangered manufacturing facilities, i.e in areas where the atmosphere is potentially explosive, all components of the measuring system, for example for a level measurement, must have an appropriate certificate.

## Dust-explosion protection (StEx)



If dusty substances with a sufficiently fine granulation are present in a sufficient quantity (for example min. layer thickness of 1 mm exceeded in an area), then there is generally the danger of a dust explosion and explosion protection measures must be taken.

The dust Ex zone comprises hazardous areas that are endangered due to combustible dusts. If level measuring instruments are used in these areas, they must have an appropriate certificate.

### 3.2 ATEX directive 94/9

#### Introduction

For standardisation of the European home market, the organs (EU/EC) have issued the "Directive 94/9/EG of the European Parliament and Council of 23. March 1997 for standardisation of legal regulations of the member states for equipment and proctective systems for use in potentially explosive atmospheres" - better known under the abreviation ATEX 95.

The Federal Republic of Germany has converted this EC directive with the publication of the explosion protection regulation (11/GSGV) on 19. December 1996 in the Federal Law Gazette into national law.

According to the new explosion protection regulation, it is only allowed to use instruments when they meet the essential health and safety requirements (annex II of directive 94/9/EG) and the prescribed conformity regulation (article 8 of directive 94/9/EG).

According to the regulations of directive ATEX 95 products are divided into product groups and categories.



- Instrument group I comprises instruments for the use in underground working including their bank-head installations.
- Instrument group II comprises instruments for use in bank-head installations and is divided in category 1 - 3.

### Categories and criteria

- Category 1: Very high safety requirement
  - Instruments for use in areas (zones) where explosive atmospheres are permanently, longterm or often present. Also in case of failures which are only seldom caused, explosion safety must be ensured.
- Category 2: High safety requirement
  - Instruments for use in areas (zones) where explosive atmospheres seldom occur. The explosion protection must also be ensured in case of often instrument failures.
- Category 3: Normal safety requirement
  - Instruments for use in areas (zones) where explosive atmospheres are not expected. As far as an explosive atmosphere occurs nevertheless, then only with a very rare probability and limited to a short period. Under normal operation, instruments of category 3 ensure the required safety degree.

According to the appropriate criteria described by the categories, the products can be coordinated to Ex protection zones.

Instruments of category 1 are determined for use in zone 0 or zone 20 (in Germany formerly zone 10). Instruments of category 2 are determined for use in zone 1 or zone 21). Instruments of category 3 are determined for use in zone 2 or zone 22.

#### Certificate

After a test authority has ensured the general safety requirements of an instrument, they will prepare a test report. This test report is basis for issuing an EC type examination certificate by the certification authority (notified authority).

The Ex mark can be added to the product, when additionally a certificate of an authority notified according to directive 97/9 on the quality assurance of the production or the products for the corresponding product group is available and when the manufacturer has issued a conformity declaration on the conformity of the products with the sample treated in the EC type approval certificate. Instruments with CE mark enjoy free movement within the European Community.



#### Gas explosion protection

Ex-certified electrical instruments are unavoidable nowadays especially in the chemical industry. They fulfil important process control functions. The PTB, TÜV and "DEKRA EXAM GmbH" test and certify the equipment in Germany according to the basic regulations of explosion protection.

### Basics of explosion protection

To create uniform guidelines for the definition of protective measures. combustible liquids and gases have been classified into explosion



groups and temperature classes in dependence on their Ex relevant characteristics.

#### **Explosion group**

The explosion groups with designation IIA, IIB, IIC concern the safe gap and/or min. ignition current ratio, whereas group IIC includes the most dangerous materials.

### Temperature classes

Combustible gases, vapours and fog are being divided into temperature classes due to their inflammation temperature. The inflammation temperature of a combustible medium is the lowest temperature of a heated wall on which the combustible medium may ignite. The ignition point is the lowest temperature where vapours from the liquid to be tested envolve in such quantities that they form inflammable mixtures together with air. The ignition point indicates up from which temperature a mixture may occur being ignited by an ignition source, the ignition temperature indicates the temperature of a surface or apparatus which can really ignite a certain mixture.

## Division of hazardous areas into zones

Hazardous areas are divided into zones according to the probable appearance of dangerous hazardous atmospheres to judge the required protective measures.

Zone 0, 1 and 2 comprise areas with combustible gases, vapours and fog.

Zone 0

Zone 0 comprises areas where dangerous and explosive atmosphere is permanently or longterm present.

Zone 1

Zone 1 comprises areas where dangerous and explosive atmospheres are sometimes expected.

Zone 2

Zone 2 comprises areas where dangerous and explosive atmospheres are seldom and then only shortterm present.

## **Dust-explosion protection**

The following criteria are particularly relevant for the hazardousness of dusts:

### Ignitable dust

Dust particles with a granulation size of more than approx. 0.4 mm are not ignitable. However fine dust produced during transport or processing of the coarse dust due to abrasion can be ignitable. The smaller the particles of a certain quantity, the larger the surface becomes which can react with the oxygen. Dust layerings which are whirled up, e.g. by air may be ignited by low surface temperatures. Due to smaller, relatively harmless deflagrations it is possible that larger dust quantities are whirled up which can ignite and due to a chain reaction can whirl up more and more dust and lead to a larger explosion.

#### Glow temperature

The glow temperature is an important factor in defining the dangerous nature (explosivity) of dusts. The glow temperature of a dust deposit is the lowest temperature of a hot surface on which a dust deposit of a certain thickness will ignite.



Zone 20, 21 and 22 are valid for combustible dusts which are defined as follows according to EN 61241-10:

Zone 20

Area in which explosive atmosphere in form of a cloud of combustible dust is permanently or longterm or often present. Note: If these conditions occur, this is generally only inside of vessels, pipelines, apparatuses etc.

Zone 21

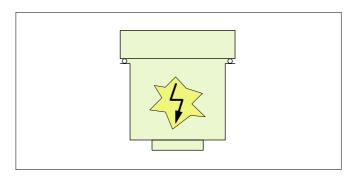
Area in which explosive atmosphere occurs sometimes in form of a cloud of combustible dust under normal operation. Note: Among these can count e.g., dust extraction and filling stations and areas where dust deposits can occur and in which an explosive concentration of combustible dust together with air can generate under normal operation.

Zone 22

Area in which under normal operation it is not expected that explosive atmospheres in form of a cloud of combustible dust occur in air, however if this occurs, then only shortterm. Note: Among these can count areas around dust containing instruments, protective systems and components in which dust can penetrate due to lack of tightness and dust deposits can be caused (e.g. mills where dust can penetrate and deposits are caused).

#### Ignition protection type

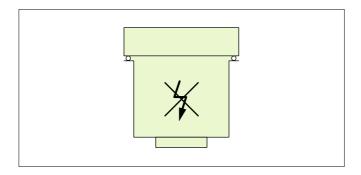
### d = pressure-tight enclosure



Components that can cause an ignition are installed in a housing that withstands explosion pressure. Due to so called ignition gaps, i.e. separating gaps with a defined width and length it is ensured that no ignition spark can expose. In addition the pressure tight housing must be resistant against possible explosion inside the housing that an ignitable spark cannot leave the instrument.

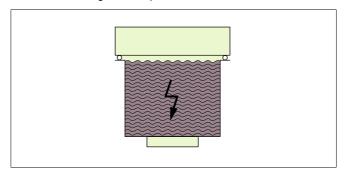


### e = increased safety



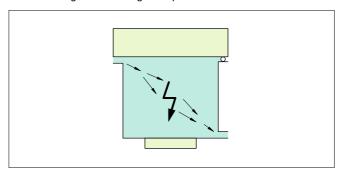
Due to constructional measures, e.g. defined min. distances of contact positions inside the instrument, it is ensured that no sparks occur during operation and that the temperatures on the components always remain below the ignition temperature.

### o = oil encapsulation



To avoid an ignition all dangerous parts become oil immersed.

### p = overpressure enclosure

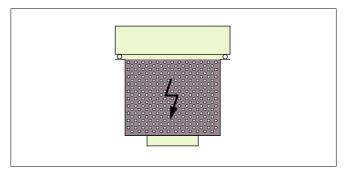


In this classification all inflammable parts are surrounded by protective gas. In practice often the following procedure is used: Inside the instrument a continuous air overpressure is built which prevents



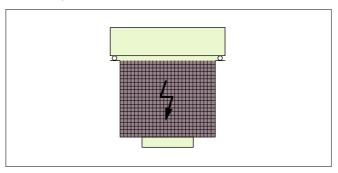
penetration of the ignitable mixture. If necessary, the housing is permanently flown through.

### q = sand enclosure



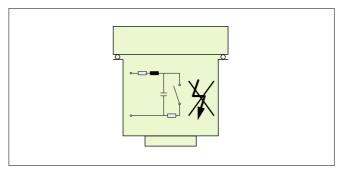
The instrument is filled with fine-grained sand. A possible arc is cooled down so that the ingnition of an explosive mixture is avoided. The surface temperature must not exceed the limit value.

### m = casting



The ignitable parts of the electrical instrument are immersed into casting so that an arc cannot leave the encapsulation and reach a explosive mixture.

### i = intrinsic safety





The letter "i" characterizes the classification "intrinsic safety" which means that the conditions for electrical circuits can be determined under which the ignition of an explosive mixture can be avoided if the electrical energy is too low. An intrinsically safe circuit ensures that an explosive gas/air mixture can neither be ignited by sparks in case of shortcircuit (capacitive stored energy) or by an interruption of the circuit (inductive stored energy) nor by heat generation.

### Proof of intrinsic safety

## Proof according to DIN EN 60079-14

The intrinsic safety of a circuit depends mainly on the safe limitation of current and voltage and hence from the merged power so that neither in normal operation nor by taking certain errors during opening and closing the circuit into account or in case of shortcircuits against ground, ignitable sparks can be caused.

To avoid spark ignition, the energy stored in a ciruit must of course remain limited. Apart from spark ignition, heat ignition by hot surfaces must also be avoided. In normal operation and in case of failure it must be ensured that the max. currents, voltages and power occurring in the intrinsically safe circuit do not cause impermissible high surface temperatures.

To maintain these criteria, not only the individual instruments in the intrinsically safe circuit must be considered but also the complete interconnection and interaction of all concerned instruments, including the connection cables. The installation conditions DIN EN 60079-14 require therefore a proof of intrinsic safety for intrinsically safe circuits, which is usually already created during planning and comprises the selection of suitable instruments as well as the testing of the selected interconnection.

For intrinsically safe citcuits with only one source delivering current, voltage and capacity to the circuit, the proof of intrinsic safety can be carried out by just comparing the safety-technical max. values:

Simple, intrinsically safe circuit							
Safe area	Ц	Appropriate instrume	Appropriate instrument				
	<u> </u>	Safety-technical max. values in an intrinsically safe cir- cuit U <sub>o</sub> , I <sub>o</sub>	Permissible outer capacitance or inductance in the intrinsically safe circuit Co, Lo	Max. power in the intrinsically safe circuit <sup>1)2)</sup>			
		Conditions: $U_o \le U_i$ $I_o \le I_i$	Conditions: $C_o \ge C_i + C_c$ $L_o \ge L_i + L_c$	Condition: $P_o \le P_i$			

- with ohmic current limitation: P<sub>o</sub> = ½ U<sub>c</sub> \* L<sub>c</sub>,
- with electronic current limitation:  $P_o = U_c * I_o$



Simple, intrinsically safe circuit								
Explosive area		Limit values with which the instrument can be operated U <sub>i</sub> , I <sub>i</sub>	Effective inner capacitance or inductance of the instrument C <sub>i</sub> , L <sub>i</sub>	Limit value of the power for the intrinsically safe instrument P <sub>i</sub>				
		Intrinsically safe equi	pment					

Tab. 22: Criteria for checking the intrinsically safe circuit

L<sub>c</sub> Line inductance C<sub>c</sub> Line capacitance

These values are appropriately entered in a chart.

Special features when considering the permissible C<sub>o</sub> and L<sub>o</sub> parameters:

In respect to the test of the max. permissible capacitance and inductance in the intrinsically safe circuit it must be noted that the max. permissible inductances Lo and capacitances Co with the corresponding instrument are not for simultaneous utilization. However, the effect is mainly present if the inductances and capacitances are effected in concentrated form in the intrinsically safe circuit. Line inductances and capacitances, however, are distributed over the complete cable length. Therefore no special measures are necessary for circuits having only inductances and capacitances of the cable.

It is different when the intrinsically safe circuit includes intrinsically safe instruments for which inner capacitances Ci as well as inner inductances L<sub>i</sub> are specified. These can be effective in the intrinsically safe circuit in concentrated form. For such circuits, you have to assume that the limit values of C<sub>o</sub> and L<sub>o</sub> must be reduced.

What to do in this case? The easiest way is to check if the manufacturer for correspoding instruments has already specified C<sub>o</sub> and Lo values which are applicable if concentrated capacitances and inductances occur at the same time. If this is not the case, you can proceed for intrinsically safe circuits with linear sources as follows:

- In circuits with only cable capacitances or cable inductances, the full values of  $\,C_{o}$  and  $\,L_{o}$  can be used.
- In circuits where either the Co value is only used up to 1 % by concentrated capacitances C<sub>i</sub> or the L<sub>o</sub> value only up to 1 % by concentrated inductance Li, also the full Co and Lo values can be
- In circuits where C<sub>i</sub> or L<sub>i</sub> are higher than 1 % of C<sub>o</sub> or L<sub>o</sub>, half the value of  $C_0$  and  $L_0$  can be used. Also the reduced  $C_0$  value applies of course as limit value for the sum of the concentrated capacitances (inner capacitance C<sub>i</sub> of the involved instruments) and the cable capacitance occurring the intrinsically safe citcuit. The same applies to the  $L_0$  value.



Example of a chart for a measuring chain consisting of an associated instrument (signal conditioning instrument VEGAMET 391) and an intrinsically safe instrument (radar sensor VEGAPULS 62).

Instru- ment type	Device name	Manu- facturer	EG type appro- val cer- tificate	U <sub>o</sub> [V]	I <sub>o</sub> [mA]	P <sub>o</sub> [mW]	L <sub>o</sub> [mH]	C <sub>o</sub> [nF]	Ex group
Appropriate instrument	VEGA- MET signal condi- tioning instru- ment XXX	VEGA	TÜV 09 ATEX XXXXX	24.4	110	662	0.5	82	IIC

Tab. 23: Proof of the intrinsic safety - Values for an associated instrument (example signal conditioning instrument)

Instru- ment type	Device name	Manu- facturer	EG type appro- val cer- tificate	U <sub>i</sub> [V]	I <sub>i</sub> [mA]	P <sub>i</sub> [mW]	L <sub>i</sub> [mH]	C <sub>i</sub> [nF]	Ex group
Intrinsi- cally safe equip- ment	Radar sensor VEGA- PULS XX	VEGA	PTB 03 ATEX XXXX X	30	131	983	0	0	IIC

Tab. 24: Proof of the intrinsic safety - Values for an intrinsically safe instrument (example radar sensor)

Instrument type		Manufacturer specifications, requirements	L <sub>c</sub> [mH]	C <sub>c</sub> [nF]
Cable	Cable inductance and capacitance	L = 700 μH/km C = 45.9 nF/km I = 600 m	0.42	27.54

Tab. 25: Proof of the intrinsic safety - Values for a cable (example)

			L <sub>i</sub> + L <sub>c</sub> [mH]	C <sub>i</sub> + C <sub>c</sub> [nF]
Intrinsically safe instru- ment and ca- ble	Total inductance and capacitance	Sum $L_i + L_c + C_i + C_c$	0.42	27.54

Tab. 26: Proof of the intrinsic safety - Total values for an intrinsically safe instrument and a cable (example)

Effective outer characteristics values	Effective inner characteristics values
--	--

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	Effective outer characteristics values		Effective inner characteristics values
U	U <sub>o</sub> = 24.4 V	≤	U <sub>i</sub> = 30 V
I	I <sub>o</sub> = 110 mA	≤	l <sub>i</sub> = 131 mA
Р	P <sub>o</sub> = 662 mW	≤	P <sub>i</sub> = 983 mW
L	L <sub>o</sub> = 0.5 mH	≥	$L_i + L_c = 0.42 \text{ mH}$
С	C <sub>o</sub> = 82 nF	2	$C_i + C_c = 27.54 \text{ nF}$

Tab. 27: Proof of the intrinsic safety for an intrinsically safe circuit (example)

#### Result:

All electrical parameters are in the permissible range. The conditions for intrinsic safety are fulfilled.

#### Additional requirements

After determining the intrinsic safety, it is the task of the person responsible in the plant to install the system according to the "Additional requirements" of EN 60079-14, particularly with respect to the identification of the circuits, maintaining the specified distances and separating the different circuits.

#### 3.3 ATEX directive 137



ATEX directive 1999/92/EG. Min. requirement to improve the health protection and the safety for employees which can be endangered by explosive atmospheres. Inofficially called ATEX 137. Named according to the relevant article 137 of the EU Treaty.

The directive includes basic safety requirements which the plant operator/employer has to implement. These are:

- Avoiding or limiting the generation of explosive atmosphere (primary explosion protection)
- Avoiding of effective ignition sources (secondary or constructive explosion protection)
- Limitation of the effect of a probable explosion to a harmless level (tertiary explosion protection)

The measures of the secondary and tertiary explosion protection must be applied subordinately. The employer must create an explosion protection document along with his danger assessment and divide areas with dangeroud explosive atmosphere into zones. For the presentation of the expansion of all individual zones, if necessary also the cubic expansion, an Ex zone plane must be created.

### 3.4 ATEX directive 95

ATEX product directive 94/9/EG. Directive for equalisation of the statutory provisions of the member states for instruments and



protective systems for intended use in hazardous areas. It specifies regulations for putting products into circulation which are used in hazardous areas. With this directive, non-electrical instruments where integrated for the first time. For example, rotating clutches can cause ignition dangers by unpermissible high heating.

Purpose of this directive is the protection of persons working in hazardous areas. The directive contains in supplement II the basic health and safety requirements which must be observed by the manufacturer and proven by respective conformity assessment procedures. Only such instruments, components and protective systems must be put into circulation which correspond to ATEX product directive 94/9/EG.

Is officially called ATEX 95. Named according to the relevant article 95 of the Treaty on European Union.

### 3.5 IECEx



The International Electrotechnical Commission, short: IEC is an international standization committee for electrotechnical and electronics standards situated in Geneva. Some standards are developed together with ISO.

The IEC consists of members, so called national committees (NC). Each NC represents the national electrotechnical interests in the IEC. Members are manufacturers, suppliers, distributors and providers, consumers and users, all levels of governmental authorities, professional instituations and trade associations as well as developers of national standards bodies.



### 4 Explosion protection USA/Canada

#### 4.1 Overview

Instruments which are used in North America in hazardous areas must be designed according to the North-American explosion protection standards and certified by an authorized test authority.

The FM and CSA certificates are also accepted by other countries outside North America.

Explosions protection standards are created by the organisations FM (USA) and CSA (Canada). Authorized test authorities for testing and certifying according to the standards are for example, FM, CSA, ITS. In the USA and in Canada, the explosive atmospheres are divided into zone 0 to 2 (can be compared with Europe) or in division 1 and 2. The combustible substances are divided into class I, II, III and group A to G.

### 4.2 FM - USA



FM Global is an American commercial industrial insurance company whose business is engineering-supported property insurance (FM stands for Factory Mutual). Its offerings include general and specialized risk management, materials research, materials testing and certifications in the area of fire protection. Risk management is understood to be the best possible avoidance of natural hazards through appropriate preventative measures.

The oldest predecessor of FM Global came into being in 1835 when the textile mill owner Zachariah Allen founded the Manufacturers Mutual Fire Insurance Company in Rhode Iceland, USA. In the course of the years, the group Associated Factory Mutual Fire Insurance Companies (in short, Factory Mutual) arose through mergers with other insurance companies. The acronym FM in its current name, FM Global, comes from this shortened form of the name. FM Global in its present form was created through the merger of the sister companies: Allendale Mutual Insurance Company, Arkwright Mutual Insurance Company and Protection Mutual Insurance Company in 1999.

FM approvals certify industrial products and consumer items as well as their use for companies worldwide. If a product or its use fulfils the requirements of the FM approval, then the "FM APPROVED" mark is issued, in order to verify that the expected function works properly and the product contributes to loss prevention.

www.fmglobal.com

### 4.3 CSA - Canada



The Canadian Standards Association (CSA) is a non-state organization that sets norms and standards, checks the safety of products and certifies them. It was founded in Canada in 1919, but in the



meantime is active worldwide. The Canadian Standards Association issues a quality mark of its own that is of significance particularly in the USA and Canada

The CSA quality mark means that a product has been checked and fulfils current safety and/or performance standards, including the relevant norms that were set or managed by the American organization for standardization (American National Standards Institute - ANSI), the Canadian Standards Association (CSA), the National Sanitation Foundation International (NSF) and others. CSA marks are used and accepted by many manufacturers, retailers, supervisory persons and inspectors nationwide in the areas of electrical engineering, gas, construction and sanitary installation in the USA and in Canada.

www.csa-international.org



### 5 Foodstuffs/Pharmaceutical

### 5.1 3-A



3-A stands for an organisation that was founded in 1920 in the USA to create standards for the equipment and facilities used in dairy factories. These standards are there to ensure product quality and thus protect the health of the consumer.

The main work of 3-A is evaluating the constructive features of instruments and systems. The organisation checks if the hygienic design is maintained. An independent authority checks with the manufacturers to make sure the specifications are applied in the correct way (3rd Party Verification) and then issues a respective certificate with test mark.

The certificate refers always to the combination instrument /process fitting.

Parallel to the FDA, 3-A publishes a list of recommended materials for the food processing industry. The principles of 3-A are also applied outside the milk industry. 3-A also gives general recommendations for the installation and operation of food processing systems.

3-A conform instruments have a 3-A logo outside on the housing.

www.3-a.com

### **European Hygienic Equipment Design Group** (EHEDG)



EHEDG is an independent merger of European companies and institutions with the objective of working out guidelines and recommendations for the hygienic production of foodstuffs. To this end, reproducible and sound scientific test methods were developed for instruments and systems.

On the basis of these test methods, EHEDG issues expert opinions on the cleanability of equipment components and systems.

EHEDG is supported in its efforts to promote hygienic food production by the topic-related network of the EU, HYFOMA. Its objective is also to establish guidelines and distribute pertinent knowledge.

www.eheda.ora

### 5.3 Food and Drug Administration (FDA)



FDA stands for Food and Drug Administration, a U.S. authority. Among other things, this authority issues a regulation on the use of productcontacting materials in the pharmaceutical, food and beverage and cosmetics industries (Code of Federal Regulations CFR).



The commission of the FDA is to protect public health in the USA. The FDA checks the safety and efficacy of human and animal drugs, biological products, medicinal products, foodstuffs and radiation emitting devices. This applies to products manufactured in the USA as well as imported products. Improving public health is also the FDA's job. It does this by supporting, among other things, the acceleration of innovations which make medicine and foodstuffs more effective, safer and more affordable.

To set down principles for the design of food processing machinery and systems, the FDA has engaged the 3-A. The FDA itself determines, for example, which materials may come into contact with foodstuffs or pharmaceuticals. The laws and regulations of the USA are laid down in the Code of Federal Regulations (CFR) and divided up into about 50 subject areas.

The area of food and pharmaceuticals is discussed under CFR 21. Synthetic materials that may come in contact with food are described in part 177. The materials are treated as if they were additives to food. Part 177 is therefore also called "Indirect food additives". Direct additives are described in Part 172

The FDA does not check materials on request but has prepared a positive list in which materials, which in principle are considered safe, are listed (GRASS = Generally Regarded As Safe). Every user must take pains to ensure that the materials he uses are "Compliant with FDA Guidelines".

Sealing materials, for example, must comply with FDA Compliance chapter 21 CFR 177.2600, "Rubber articles for repeated use".

www.fda.gov





### 6 Ship approval

There are instruments for use on ships that are type-examination tested and certified by ship classification societies. In the context of the International Association of Classification Societies, IACS, the following member organizations are listed.

### www.iacs.org.uk

- American Bureau of Shipping (ABS), USA
- Bureau Veritas (BV), France
- China Classification Society (CCS), China
- Det Norske Veritas (DNV), Norway
- Germanischer Lloyd (GL), Germany
- Korean Register of Shipping (KRS), Korea
- Lloyd's Register of Shipping (LRS), England
- Nippon Kaiji Kyokai (NKK), Japan Registro Italiano Navale (RINA), Italy
- Maritime Register of Shipping (RS), Russia

The requirements for use on ships refer primarily to on-board supply system, vibration and humidity effects.

### ABS (USA)



Founded in 1862, the American Bureau of Shipping (ABS) with headquarters in Houston, Texas, is one of the leading classification societies worldwide for ships, oil rigs and other maritime buildings as well as their components at over 400 locations in more than 100 countries. It was founded as the "American Shipmasters' Association" in 1862 by John Divine Jones, renamed to "American Bureau of Shipping" in 1898 and officially recognised by the USA in 1920 in the United States Government Merchant Marine Act, Section 27.

www.eagle.org

### 6.2 BV (France)



Bureau Veritas S.A. is a technical testing organization that emerged from a ship classification society founded in Antwerp in 1828. Today its headquarters are in Paris. In the course of the years, its business interest has extended itself to include, besides ships, many other areas of industry with regard to inspection, assurance and certification of quality, health and social environment. In 2006 Bureau Veritas was represented in more than 150 countries and has about 700 agencies, laboratories and offices at its disposal worldwide.

www.buerauveritas.com



### 6.3 CCS (China)

The China Classification Society (CCS), founded in 1965, is the only facility in China responsible for classifications. CCS offers services for shipping, shipbuilding, offshore and the accompanying processing industries as well as marine insurance. It sets classification requirements and offers independent, objective and integral classification and legally specified services for ship and offshore facilities, for support and protection of lives and property at sea and for avoidance of pollution.

www.ccs.org.cn

### 6.4 DNV (Norway)



Det Norske Veritas (DNV) is an independent foundation. DNV was founded in Oslo, Norway in 1864. The purpose of the organisation is to protect lives, property and the environment. It has branch offices in more than one hundred countries and over 8,000 employees. The organisation consists of four business sectors: Maritime, Energy, Industry and IT Global Services. DNV is one of the leading enterprises worldwide in the areas of ship classification (approximately 18 % of the worldwide ship fleet), management system certification (more than 60,000 valid certificates) and services for the energy industry (e.g. the technical supervision of offshore facilities).

www.dnv.com

### 6.5 GL (Germany)



German Lloyd is a ship classification society. The society deals with the care and support of the itinerant fleet classified at German Lloyd and the supervision of new ship builds. Its supervisory activities also cover technical maritime constructions and offshore equipment, partly also plant construction. The necessary scientific methods are developed further by German Lloyd both in the area of ship calculation and machine technology.

www.gl-group.com

### 6.6 KRS (Korea)



Korean Register of Shipping (KRs) is a classification society that was founded in Korea. It offers authentication and certification services for ships and ship constructions with regard to design, construction and servicing. KR guarantees the security of lives and property at sea as well as environmental protection. The company has 560 employees in 45 offices worldwide. Its headquarters are in DaeJeon, South Korea. KR also offers certification services for different lines of business like education and training, navy and coast guard ships, renewable energy supplies, etc.

#### www.krs.co.kr

### 6.7 LRS (Great Britain)



Lloyd's Register Group (LR) in London (additional headquarters: Houston and Hong Kong) is a ship classification society and independent risk management organization which offers services for risk assessment and reduction as well as certifications (e.g. according to ISO 9001:2000, ISO 14001:2004, OSHAS, EMAS etc.). Lloyd's Register Society is the first and oldest classification society (1764) that set up rules for the maximization of safety during the construction and maintenance of ships. In the late 20th century, the organization extended its activities from its origins in the shipping sector (Lloyd's Register of Shipping) to other sectors, e.g. the railroad system.

www.lr.org

### 6.8 NKK (Japan)



The origins of Nippon Kaiji Kyokai date back to the foundation of Teikoku Kaiji Kyokai (the Imperial Marine Association) in Tokyo in November 1899. This association was founded to promote and regulate the legal aspect and development of the shipping and shipbuilding industry in Japan. ClassNK was focussed exclusively on the area of shipbuilding after its foundation, but today has additional functions as a certification organization and as a service provider for technical supervision.

www.classnk.or.jp

### 6.9 RINA (Italy)



The company deals mainly with the technical supervision and classification of ships. Further areas of business are technical certifications and risk management in the areas of traffic and infrastructure as well as technical consulting and support for enterprises in many different commercial sectors. The company domicile and administration are in Genoa. Over 1,300 people work for RINA in approximately 100 branch offices in Italy and 32 other countries. RINA was founded in Genoa in 1861 under the name Registro Italiano by local shipping companies and ship owners, as a private foundation to end dependence on foreign classification societies and to lower insurance costs.

www.rina.org



### 6.10 RS (Russia)

The classification society Russian Register was set up on December 31st, 1913, as the result of long-standing experience in the field of technical supervision of ships. In 1923 Russian Register was renamed



as Register of the Soviet Union and again later as Russian Maritime Register of Shipping (RS). The RS is a member of the International Association of Classification Societies (IACS) since 1969. Primary objectives: assurance of safe life at sea, reliable navigation of ships, safe transport of goods at sea and in inland waters, promotion of environmental protection. To guarantee this, RS develops and extends regulations based on extensive research as well as the requirements of international agreements and guidelines. All RS activities ensure through the maritime society a high standard of safe navigation.

www.rs-head.spb.ru

### 7 Functional safety (SIL)

### 7.1 Overview

### Objective

Functional safety acc. to IEC 61508 serves to protect persons, technical systems and the environment with the means of MSR technology.

Components that are used for safety instrumented system applications must therefore possess a corresponding level of "functional safety" (SIL = Safety Integrity Level).

## 7.2 Functional safety according to IEC 61508 and IEC 61511 (SIL)

#### **Basics**

All around the globe, the safety requirements for the protection of man and environment are getting higher and higher and the demand for the implementation of the best possible technology louder and louder.

The norms IEC 61508 and IEC 61511 set the worldwide standard for a uniform and comparable evaluation of device safety, which contributes to international legal security.

The objective is failure prevention and fault control in every component of a measuring chain for safety instrumented systems (SIS).

The mentioned norms define the type of statistical risk evaluation as well as measures and methods for the design of sensors, actuators and logic processing.

#### SIL classification

The level of "functional safety" of an SIS is divided up into gradations, from SIL1 to SIL4 (SIL = Safety Integrity Level). The majority of SISs have a classification of SIL1 and SIL2, in some cases also SIL3.

Derived from IEC 61508, the IEC 61511 determines for users in the process industry how components with an appropriate SIL qualification are integrated into a safety instrumented system.



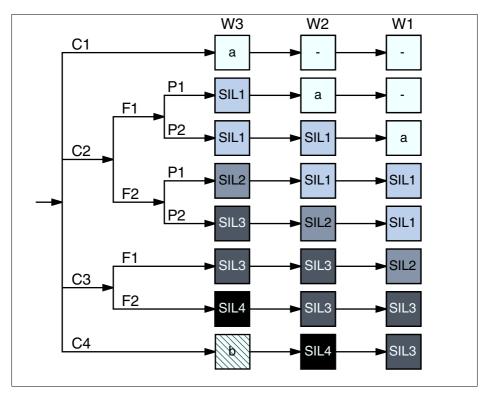


Fig. 1: Risk graph from IEC 61508 and IEC 61511

- C Measure of damages
- F Length of stay in the dangerous zone
- P Danger avoidance
- W Probability of the unwanted event
- a No special safety requirements
- b One single E/E/PE system not sufficient

### C - Extent of damage

- C1 Slight injury
- C2 Serious irreversible injuries to one or more persons or death of a person
- C3 Death of several persons/long-term, sizable and harmful environmental effects
- C4 Disastrous consequences, many deaths

### F - Length of stay in the dangerous zone

- F1 Seldom to often
- F2 Frequent to continuous

### P - Danger avoidance

P1 - Possible under certain conditions



• P2 - Hardly possible

### W - Probability of the unwanted event

- W1 Very low
- W2 Low
- W3 Relatively high

#### SIL documentation

The qualification of components as per IEC 61508 and/or IEC 61511 is documented by a safety manual on the topic of functional safety. All safety-relevant characteristics and information that users and planners need for project planning and operation of the safety instrumented system are summarized here. You can download this documentation from our homepage <a href="https://www.vega.com">www.vega.com</a>.

## Instruments with SIL qualification

If you order an instrument with SIL qualification (optional at extra charge), you get:

- An instrument with permanently activated SIL functionality (for continuously measuring sensors)
- "SIL qualification" on the type plate
- The safety manual with all safety-relevant data
- The complete instrument documentation



### 8 Overfill protection according to WHG

### 8.1 Overview



In Germany, an overfill protection acc. to WHG (Water Resources Act) is required when handling water-endangering substances. In paragraph 19 of WHG and in the associated state regulations concerning systems for storing, filling and transhipping water-endangering substances, the implementation of an overfill protection system is mandated. All components of an overfill protection system for containers storing water-endangering liquids must comply with the approval principles for overfill protection. The sensors in such overfill protection systems require approval.

### 8.2 Description

#### Basics, scope

The Water Resources Act (WHG) of the Federal Government, as a legal framework, is the basis for the water laws of the federal states and is one of the most substantial laws dealing with environmental protection. The WHG requires overfill protection systems to be installed on all containers for water-endangering liquids. The purpose of an overfill protection system as per the WHG is to monitor the level of water-endangering liquids and to interrupt the filling process at the right time before the permissible level in the container is reached or to trigger an acoustical or visual alarm.

#### Approval as overfill protection

The products that have to be monitored are described in the catalogue of water endangering substances (KWS) and divided up into water endangerment classes 1 - 3. The Water Resources Act and the associated state regulations concerning systems for the storage, filling and transhipping of water-endangering substances (VAwS) make the use of overfill protection systems mandatory. Such an overfill protection system must have an approval. TÜV Hanover issues test certificates concerning functional performance and compliance with the approval principles for overfill protection (ZG-ÜS). On the basis of this test, the German Institute for Civil Engineering (DIBt) grants a general technical approval that is valid nationwide. The field of application of overfill protection systems and the approval obligation of such systems is legally anchored. The functionality of such systems is thus guaranteed.

### www.dibt.de

#### **VLAREM / BUWAL**

Similar regulations exist in Belgium and Switzerland.

In parts of Belgium it is the VLAREM. You can get further information from AIB Vincotte at www.vincotte.com.

In Switzerland the guideline is called BUWAL. The Federal Office for the Environment (BAFU) is in charge. You can find further information at www.bafu.admin.ch.



### 9 Fieldbus systems

#### Overview

### Description

A fieldbus is an industrial communication system that connects a variety of field instruments such as sensing elements (sensors), final controlling elements and drives (actuators) with a control device.

#### Development

Fieldbus technology was developed in the eighties to replace the parallel wiring of binary signals (common up to that time) as well as analogue signal transmission with digital communication technology. Many different fieldbus systems with different features are established on the market today. Since 1999, fieldbusses are being standardized worldwide through the IEC 61158 norm ("Digital data communication for measurement and control - Fieldbus for use in industrial control systems").

### 92 HART



Highway Addressable Remote Transducer (HART) is a standardized, widely-used communication system for the construction of industrial fieldbusses. It enables the digital communication of several participants (field instruments) via a common data bus. HART particularly makes use of the also widely-used 4 ... 20 mA standard (for transmission of analogue sensor signals). The existing cables of an older system can be used directly and both systems operated parallel to each other.

#### Development

The company Rosemount developed HART in the 1980's for its own field instruments. The HART standard was created by the HART Communication Foundation (HCF) in 1989. The domicile of the HART Communication Foundation in Europe is in Basel (Switzerland).

#### Data transmission

The data transmission is carried out via Frequency Shift Keying (FSK) in compliance with the Bell 202 Standard. A high-frequency electric oscillation (+/-0.5 mA) is superimposed on the low-frequency analogue signal. A digital "1" is represented by the frequency 1.2 kHz (1200 Hz) and digital "0" by the frequency 2.2 kHz (2200 Hz). HART specifies several protocol levels in the OSI model and permits the transmission of process and diagnostic information as well as control signals between the field instruments and the primary control system. Standardized parameter sets can be used for manufacturer independent operation of all HART instruments. Most well-known manufacturers of sensors (field instruments) offer instruments with - in some cases optional – HART communication. Typical examples are measuring transducers for the measurement of mechanical and electrical quantities.

www.hartcomm2.org



### 9.3 Profibus



The history of Profibus goes back to a publicly-sponsored, joint research project in Germany in 1987, for which 21 companies and institutes had drawn up a project outline plan called "Fieldbus". The objective was the realization and distribution of a bit serial fieldbus, whose foundation should be laid through the standardization of the field device interface. To this end, relevant member companies agreed to support a common technical concept for manufacturing and process automation. As a first step, the complex communications protocol Profibus FMS (Fieldbus Message Specification), especially designed for demanding communication tasks, was specified. In later steps as of 1993, the specification of the more simply constructed and therefore considerably faster protocol Profibus DP (Decentralized Peripherals) was carried out.

Versions, data transmission

Profibus exists in three versions, of which DP is the most used: Profibus DP (Decentralized Periphery) for control of sensors and actuators through a central control in production engineering. The many possible standard diagnostic functions are a major feature here. Another important application is the linking of "distributed intelligence", i.e. the networking of multiple controls among each other (similar to Profibus FMS). Data rates up to 12 Mbit/sec. on twisted two-wire cables and/or fibre-optic cables are possible.

In process and production engineering, Profibus PA (Process Automation) is implemented for controlling measuring instruments via a process control system. This version of Profibus is suitable for explosion-prone areas (Ex zone 0 and 1). Here, only a weak current flows through the bus cables of an intrinsically safe electrical circuit, ensuring that no incendiary sparks can arise, even in case of failure.

www.profibus.com

### 9.4 Foundation Fieldbus



The Fieldbus Foundation is an organization resident in the USA and composed mainly of companies who develop and produce fieldbus systems or components. It was founded in September 1994 through the merger of two organizations who were autonomous up to that time, the WorldFIP North America and the Interoperable Systems Project (ISP). At the time of the merger it encompassed approx. 350 member companies. The objective of the organization is to develop common standards and submit applicable standardization proposals, e.g. to the IEC.

Versions, data transmission

Foundation Fieldbus H1 uses the same bus physics as Profibus PA, as per IEC 61158-2 with a transfer rate of 31.25 Kbit/s. Intrinsically safe, bus-supplied instruments can be integrated into a network with this technology. An information signal from the transmitting instrument is superimposed onto the supply voltage provided by the bus for supplying the instruments. This signal is created through current



modulation. H1 provides two different device classes: Basic field devices offer the typical field device functionality. These instruments comprise a function block application, act as a publisher and subscriber of process variables (PVs), transmit alarms and trends, and provide server functionality for host access and management functions. Link master devices can also function as a link active scheduler and time master. They are used for bus interfaces in process control systems or in linking devices.

Four different device classes are specified with Foundation Fieldbus HSE: Host devices are PCs or control systems with Ethernet connection which do not contain any function blocks or management objects themselves but communicate with HSE devices via Ethernet. A linking device is connected to an Ethernet network and serves multiple Foundation Fieldbus H1 segments. Foreign I/O gateways are integration components connecting to foreign fieldbusses, such as e.g. Profibus DP. Ethernet devices represent the last class. These field instruments integrate directly into the Ethernet network.

www.fieldbus.org



### 10 Test certificates and factory certifications

### 10.1 General information

#### Availability

The availability of test certificates and factory certifications can change depending on the selected instrument configuration and version.

Talk with our application engineers or find out what is available at <a href="https://www.vega.com/configurator">www.vega.com/configurator</a>.

#### 10.2 Acc. to DIN EN 10204 - for instruments

### Factory certification 2.1

### Factory certification 2.1 for instruments (Certificate A)

Certification verifying that the products listed in the factory certification correspond with the stipulations of the order.

### Factory certification 2.1 - Special features

## Factory certification 2.1 for instruments with the assurance of special features (Certificate A)

Certification verifying that the products listed in the factory certification correspond with the stipulations of the order. Also with instrument-specific assurance of special features without test protocols, such as e.g. surface roughness as per AQL, oil and grease free, FDA conformity, declaration of no objection for RADAR radiation, ROHS statement, etc.

### Acceptance test certificate 3.1

### Acceptance test certificate 3.1 for instruments (Certificate B)

Certification verifying that the product mentioned in the acceptance test certificate corresponds to the technical delivery terms specified in the order and was checked in all production phases and subjected to a final inspection, in order to guarantee its proper functioning as well as compliance with the high VEGA quality standard. Includes information about the standard tests carried out and successfully passed according to an instrument-specific test plan.

# Acceptance test certificate 3.1 - Special features

## Acceptance test certificate 3.1 for instruments with assurance of special features (Certificate B)

Certification verifying that the product mentioned in the acceptance test certificate corresponds to the technical delivery terms specified in the order and was checked in all production phases and subjected to a final inspection, in order to guarantee its proper functioning as well as compliance with the high VEGA quality standard. Includes information about the supplementary special test carried out and passed, which is not included in the instrument-specific test plan and therefore has to be additionally carried out. The test procedure and test protocol of the special test are also documented in the approval certificate.

36200-EN-110921



### 10.3 Acc. to DIN EN 10204 - For materials

### Factory certification 2.2 -Material

### Factory certification 2.2 for material (Certificate H)

Certificate verifying that the mechanical parts mentioned in the factory certification correspond with the specifications in the order. Documented by material certificate 3.1 with information about the test results from non-specific tests.

The material certificate 3.1 can no longer be directly related to the parts listed in the certification because the identification number (melt number) is no longer recognizable due to a follow-up surface treatment (e.g. polishing, coating).

### Acceptance test certificate 3.1 - Material

### Acceptance test certificate 3.1 for material (Certificate C)

Certificate verifying that the mechanical parts mentioned in the factory certification correspond with the specifications in the order. Documented by material certificate 3.1 with information about the test results from specific tests.

The acceptance test certificate 3.1 of the material manufacturer can be directly related to the parts listed in the certification, because these are clearly marked with the identification number (melt number). Documented by acceptance test certificate 3.1 of the material manufacturer with information about the test results from specific tests.

### 10.4 VEGA company standard

### Inspection certificate -Final test station

### Inspection certificate with measurement results from the final test station

Certification verifying that the product mentioned in the inspection certificate corresponds to the technical features specified in the order confirmation and was checked in all production phases and subjected to a final inspection, in order to guarantee its proper functioning as well as compliance with the high VEGA quality standard. Includes measurement results from the instrument-specific final test station.

### Inspection certificate -Reference measuring track

### Inspection certificate with measurement results from the reference measuring track

Certification verifying that the product mentioned in the inspection certificate corresponds to the technical features specified in the order confirmation and was checked in all production phases and subjected to a final inspection, in order to guarantee its proper functioning as well as compliance with the high VEGA quality standard. Includes measurement results from the reference measuring track (by default, five measuring points linearly distributed along the adjustment or measuring range of the sensor).



## VEGA

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All statements concerning scope of delivery, application, practical use and operating conditions of the sensors and processing systems correspond to the information available at the time of printing.

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