

RECHNER
WISSEN - KNOWLEDGE

*Food and Pharma
Basics*



Food and Pharma Hygienic Design Cleanability

TABLE OF CONTENT

	Table of Contend	Page
Norms and Directives	Motivation	4 - 5
	Sources of Information	6
	European Standards and Directives	7 - 8
	Declaration of Conformity Basics and Examples	9 - 14
	Tri-Clamp / Tri-Clover	15 - 22
Materials	Food Contact Materials Basics and Directives	23 - 25
	Plastics	26
	Metalls	27

SAFE PRODUCTS

CONSUMER PROTECTION

OPTIMIZATION OF THE
CLEANING PROCESSES

REDUCTION OF THE
CLEANING AND
MAINTENANCE TIMES

MOTIVATION

In process technology and plant engineering, the definition of „hygienic design“ refers to the design of machines and plants with consideration of the cleanability of the system.

This is always relevant where products are manufactured that can be dangerous for the consumer due to germs or contamination and also where the product can turn out to be unusable, which represents a loss for the manufacturer.

Hygienic design is for example relevant in the following business areas:

- FOOD INDUSTRY (HUMANS AND ANIMALS)
- BEVERAGE INDUSTRY
- PHARMACEUTICAL INDUSTRY
- CHEMICAL INDUSTRY
- COSMETIC INDUSTRY
- BIOTECHNOLOGY

Hygienic design must be considered at all parts of the plant that come into direct contact with the product to be produced. An important factor for the aforementioned industries is the optimization of the cleanability, with the aim to:

- PRODUCE SAFE PRODUCTS
- REDUCE DOWNTIME
- LOW CLEANING AND MAINTENANCE TIMES

In order to achieve this targets, a number of standards have been developed which must be taken into account in the design of machines and plants.

Here, the individual elements such as piping and containers must be planned taking into account the rules for hygienic design. Materials, surface quality, avoidance of gaps and dead spaces as well as the drainage of liquids and operating materials are elementary, for example.

When planning machines and systems, the state of the art must be taken into account, with consideration of legal guidelines, the practically well-established and the feasible.

AS A GUIDELINE

AS BEST AS POSSIBLE
AT LEAST AS GOOD AS NECESSARY

Designers must analyse the installations and assess the risks. In doing so they must consider the following:

WHICH AREAS ARE IN CONTACT WITH THE PRODUCT?

WHICH GUIDELINES MUST BE OBSERVED?

WHICH MATERIALS CAN BE USED (INERT, NON-TOXIC)?

WHAT TEMPERATURE STABILITY MUST BE CONSIDERED?

WHAT IS THE SURFACE QUALITY? Surfaces and joints must be smooth. There must not be any gaps or crevices in which organic substances or micro-organisms can accumulate.

THE NUMBER OF CONNECTIONS SHOULD BE MINIMIZED.

CLEANABILITY? All areas that come into contact with the product must be easy to clean. There must be no dead spaces.

The complete draining of liquids, whether from the product or from the cleaning or disinfecting agents, must be ensured.

In addition, these aspects are so important for the manufacturer because possible impurities or contaminations of the product and the associated recall actions would cause great damages to the image and losses.

GPSG
GERÄTE UND
PRODUKTSICHERHEITSGESETZ
/ EQUIPMENT AND PRODUCT
SAFETY ACT

CONSUMER PROTECTION

RISK REDUCTION

PREVENT CALLBACKS

PREVENT DAMAGE TO IMAGE

Regulation (EU) No. 1935/2004

Traceability Regulation (EU) 10/2011 Cleanability
Plastics Regulation (EU) No. 2006/42/EG EHEDG

Process optimization

Regulation (EU) No. 178/2002 No threads expert
Stainless Steel FDA

Smooth surface Food Safety IECEx

Consumer protection

Hygienic Design

Customer
centricity

Avoid dead
spaces

Regulation (EU) 2023/2006

Capacitive Sensors

Quality

Precision

Reliability

Reduce downtime

GMP
ATEX

SOURCES OF INFORMATION

COMPETENT
INSTITUTIONS
HELP WITH
RECOMMEN-
DATIONS AND
GUIDELINES

In general, different specifications, regulations and requirements are available for „Hygienic Design“. The national and EU directives must be observed. The following list names some of the most important institutions:

- EFSA (European Food Safety Authority)
- EHEDG (European Hygienic Engineering and Design Group)
- EU Guidelines
- FDA (Food and Drug Administration)
- GMP (Good Manufacturing Practice)
- ISPE (International Society for Pharmaceutical Engineering)
- ISO (Internationale Organisation für Normung)
- DIN (Deutsches Institut für Normung)
- DGUV (Deutsche Gesetzliche Unfallversicherung / German Accident insurance)
- AMI (North American Meat Institute)



EUROPEAN STANDARDS

The following European standards and directives are of interest to anyone who has to deal with the subject of food safety:

- **EN 1672-2:2009**
Food processing machines / General principles for design / Part 2: Hygienic Design requirements
- **EN ISO 14 159:2008**
Safety of machines– Hygienic requirements for the design of machinery
- **EN 16 001**
Energy management to improve energy efficiency
- **Maschine Directive 2006/42/EG**
- **Dokument 13 EHEDG Guideline Hygienic,**
Design of apparatus for open processes, which was made in cooperation with 3-A and NSF International

STANDARDS
AND
GUIDELINES
DEFINE THE
FRAMEWORK
TO BE
FULFILLED



EUROPEAN DIRECTIVES

Some relevant directives with regard to the food safety of equipment and products intended to come into contact with food are listed below:

EU DIRECTIVES HELP TO
CREATE HARMONIZED
STANDARDS

THEY ARE THE BASIS
FOR A HIGH LEVEL
OF PROTECTION FOR
HUMAN HEALTH

CONCERNED ARE PROD-
UCTS THAT DIRECTLY OR
INDIRECTLY COME INTO
CONTACT WITH FOOD-
STUFFS

Document No.	Document Title	Version
Regulation (EC) 178/2002	Regulation (EC) No. 178/2002 of the European Parliament and of the Council of 28. January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety	1/28/2002
Regulation (EG) 1935/2004	Regulation (EC) No. 1935/2004 of the European Parliament and of the Council of 27. October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC	10/27/2004
Regulation EC 2023/2006	Regulation (EC) No. 2023/2006 of 22. December 2006 on good manufacturing practice for materials and articles intended to come into contact with food.	12/22/2006
Regulation EC 1895/2005	Regulation (EC) No. 1895/2005 of 18 November 2005 on the restriction of use of certain epoxy derivates in materials and articles intended to come into contact with food. (Limitation of: BADGE NOGE, BGDGE)	11/18/2005
Regulation (EU) 10/2011	Regulation (EU) No. 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food (This directive also lists the food simulants used for inertness testing)	1/14/2011
Regulation (EG) Nr. 282/2008	Commission Regulation (EC) No. 282/2008 of 27 March 2008 on recycled plastic materials and articles intended to come into contact with foods and amending Regulation (EC) No. 2023/2006.	3/27/2008
Regulation (EU) 2016/1416	Commission Regulation (EU) 2016/1416 of 24 August 2016 amending and correcting Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food.	8/24/2016
Regulation (EU) 2018/831	Commission Regulation (EU) 2018/831 of 5 June 2018 amending Regulation (EU) No. 2011 on plastic materials and articles intended to come into contact with food.	6/5/2018
Regulation (EU) 2019/37	Commission Regulation (EU) 2019/37 of 10 January 2019 amending and correcting Regulation (EU) No. 10/2011 on plastic materials and articles intended to come into contact with food.	1/10/2019



DECLARATION OF CONFORMITY

Regulation (EC) 1935/2004 is based on the principle that materials and articles intended to come into direct or indirect contact with food must be adequately inert to ensure that they do not endanger human health.

All materials and articles intended to come into contact with food should comply with the requirements of this Regulation.

Regulation (EC) No. 2023/2006 on good manufacturing practice for materials intended to come into contact with food lays down rules on good manufacturing practice (GMP for the groups of materials and articles listed in Annex 1 to Regulation (EC) No. 1935/2004.

The area of validity is defined as follows:

Article 2 of Regulation 2023/2006

This regulation shall apply to all sectors and to all stages of manufacture, processing and distribution of materials and articles, up to but excluding the production of starting substances.

The definitions in this Regulation are described under:

Article 3 of Regulation 2023/2006

- **Quality Assurance System**
means the total sum of the organised and documented arrangements made with the purpose of ensuring that materials and articles are of the quality required to ensure conformity with the rules applicable to them and the quality standards necessary for their intended use.
- **Quality Control System**
means the systematic application of measures established within the quality assurance system that ensure compliance of starting materials and intermediate and finished materials and articles with the specification determined in the quality assurance system
- **Non-Food-Contact Side“**
means the surface of the material or article that is not directly in contact with food.
- **Food-Contact Side“**
means the surface of a material or article that is directly in contact with the food.

GMP

EXCELLENT
QUALITY

FOR RECHNER SENSORS IS
QUALITY MANAGEMENT
WITH RELIABLE
DOCUMENTATION
PART OF THE
COMPANY'S OBJECTIVES.



DECLARATION OF CONFORMITY

THE CONFORMITY
DECLARATION
(EC) 1935/2005
CONFIRMS
THE COMPLETE
TRACEABILITY
OF THE
FOOD-CONTACT
MATERIALS

FOOD-CONTACT
TRACEABILITY
GMP



Manufacturers of products and materials which come into contact with food and for which individual measures are mandatory shall, in accordance with:

[Article 16 of Directive 1935/2004](#)

be accompanied by a written declaration stating that the food-contact materials comply with the rules applicable to them.

Directive 1935/2004 also includes the assurance of the traceability of materials and articles at all stages in order to facilitate controls, the recall of defective products, consumer information and the establishment of liability.

According to

[Article 17 of directive 1935/2004](#)

With due regard to technological feasibility, business operators shall have in place systems and procedures to allow identification of the businesses from which and to which materials or articles and, where appropriate, substances or products covered by this Regulation and its implementing measures used in their manufacture are supplied. That information shall be made available to the competent authorities on demand.

All our sensors have an individual ID number. An appropriate documentation is guaranteed.

In accordance with

[Article 3 of directive 1935/2004](#)

all materials and articles that come in contact with food shall be manufactured in compliance with good manufacturing practice (GMP) so that, under normal or foreseeable conditions of use, they do not transfer their constituents to food in quantities which could:

- endanger human health or
- bring about an unacceptable change in the composition of the food or
- bring about a deterioration in the organoleptic characteristics thereof.

DECLARATION OF CONFORMITY

The Regulation (EG) 10/2011 is a specific measure within the meaning of Article 5(1) of Regulation (EC) No 1935/2004. This Regulation should establish the specific rules for plastic materials and articles to be applied for their safe use.

Article 15 of Regulation 10/2011 specifies as follows:

(1) At the marketing stages other than at the retail stage, a written declaration in accordance with Article 16 of Regulation (EC) No. 1935/2004 shall be available for plastic materials and articles, products from intermediate stages of their manufacturing as well as for the substances intended for the manufacturing of those materials and articles.

(2) The written declaration referred to in paragraph 1 shall be issued by the business operator and shall contain the information laid down in Annex IV.

(3) The written declaration shall permit an easy identification of the materials, articles or products from intermediate stages of manufacturer substances for which it is issued. It shall be renewed when substantial changes in the composition or production occur that bring about changes in the migration from the materials or articles or when new scientific data becomes available.

EASY IDENTIFICATION OF

THE MATERIALS THAT MAY IN
CONTACT WITH FOOD

AND OF

THE SUPPLY CHAIN OF THESE
MATERIALS

CONFORMITY DECLARATION

REGULATION (EC)
10/2011

FOOD-CONTACT
TRACEABILITY
GMP



Article 15 of Regulation 10/2011 describes the content of the declaration of conformity:

1. The identity and address of the business operator issuing the declaration of compliance;
2. The identity and address of the business operator which manufactures or imports the plastic materials or articles or products from intermediate stages of their manufacturing or the substance intended for the manufacturing of those materials and articles;
3. The identity of the materials, the articles, products from intermediate stages of manufacture or the substances intended for the manufacturing of those materials or articles;
4. The date of the declaration;
5. Confirmation that the plastic materials or articles, products from intermediate stages of manufacture or the substances meet relevant requirements laid down in this Regulation and Regulation (EC) No. 1935/2004;
6. Adequate information relative to the substances used or products of degradation thereof for which restrictions and/or specifications are set out in Annex I and II to this Regulation to allow the downstream business operators to ensure compliance with those restrictions;
7. Adequate information relative to the substances which are subject to a restriction in food, obtained by experimental data or theoretical calculation about the level of their specific migration and, where appropriate, purity criteria in accordance with Directives 2008/60/EC, 95/45/EC and 2008/84/EC, to enable the user of these materials or articles to comply with the relevant EU provisions or, in their absence, with national provisions applicable to food;
8. Specifications on the use of the material or article, such as:
 - i) type of types of food with which it is intended to be put in contact;
 - ii) time and temperature of treatment and storage in contact with the food,
 - iii) ratio of food contact surface area to volume used to establish the compliance of the material or article;
9. When a functional barrier is used in a multi-layer material or article, the confirmation that the material or article complies with the requirement of Article 13 (2), (3) and (4) or Article 14 (2) and (3) of this Regulation.

REGULATION (E
10/2011

FOOD-CONTACT
TRACEABILITY
GMP

CONFORMITY DECLARATION

Example of a declaration of Conformity from Rechner Sensors:

Konformitätserklärung		Declaration of Conformity	
<p>Verordnung (EG) Nr. 1831/2003 über Materialien und Gegenstände, die dazu bestimmt sind, mit Lebensmitteln in Berührung zu kommen.</p> <p>Wir RECHNER Industrie-Elektronik GmbH, Gaußstraße 6-10, 68623 Lampertheim</p> <p>erklären hiermit, dass die nachstehend aufgeführten, von uns für die Herstellung unserer Sensoren verwendeten Gehäusematerialien, die in Kontakt mit Lebensmitteln kommen können, der Verordnung (EG) 1831/2003 entsprechen.</p> <p>Welches Gehäusematerial für den von Ihnen verwendeten Sensor eingesetzt wurde, entnehmen Sie bitte dem Datenblatt des Sensors.</p> <p>Es liegt in der Verantwortung des Anwenders zu prüfen, ob die Materialien für den vorgesehenen Anwendungszweck geeignet sind.</p>		<p>Regulation (EC) No. 1831/2003 on materials and articles intended to come into contact with food.</p> <p>We RECHNER Industrie-Elektronik GmbH, Gaußstraße 6-10, 68623 Lampertheim</p> <p>declare herewith that the below listed and for the production of our sensors used housing materials, that could be in contact with food, are in conformity to the regulation (EC) No. 1831/2003.</p> <p>For details, which material is used for the specific product please see the data sheet of the sensor.</p> <p>It is the responsibility of the user to check whether the materials are suitable for the intended application.</p>	
Kurzbeschreibung / Short description	Material	FDA-No.	Bitte Anhang Nr. / See Appendix No.
XXXXXXXX	Polyetheretherketone / Polyetheretherketone	XXXXXXXX	Nr. 1
<p>Besteller / Customer: XXXXXX Aktivier. Besteller / Article No. Customer: XXXXX</p> <p>Artikel Nr. / Article No.: XXXXXX Artikelname / Article name: XXXXXX</p> <p>Dieses Dokument hat eine Gültigkeit bis zu 24 Monate. This document is valid for up to 24 months. Lampertheim, 14.07.2020</p>			

RECHNER SENSORS	
<p>Anhang Verordnung (EG) Nr. 1831/2003</p> <p>Eine Konformitätserklärung ist somit eigenverantwortlich. Laut der Verordnung (EG) Nr. 1831/2003 sollte die Rückverfolgbarkeit von Materialien und Gegenständen, die dazu bestimmt sind, mit Lebensmitteln in Berührung zu kommen, auf allen Stufen gewährleistet sein, um Kontrollen, den Rückruf fehlerhafter Produkte, die Untersuchung der Verbraucher und die Feststellung der Haftung zu erleichtern. Die Unternehmer sollten zumindest jene Firmen ermitteln können, von denen sie die Materialien und Gegenstände bezogen oder an die sie solche abgegeben haben.</p>	<p>Appendix Regulation (EC) No. 1831/2003</p> <p>According to the regulation (EC) No. 1831/2003 the traceability of materials and articles shall be ensured at all stages in order to facilitate control, the recall of defective products, consumer information and the attribution of responsibility. With due regard to technological feasibility, business operators shall have in place systems and procedures to allow identification of the business from which and to which materials or articles and, where appropriate, substances or products covered by this regulation and its implementing measures used in their manufacture are supplied.</p>
<p>GMF - Verordnung Verordnung (EG) 2023/2006 über gute Herstellungspraxis für Materialien und Gegenstände, die dazu bestimmt sind, mit Lebensmitteln in Berührung zu kommen.</p> <p>Set 1. August 2009 gilt die Verordnung (EG) 2023 über gute Herstellungspraxis für Materialien und Gegenstände, die dazu bestimmt sind, mit Lebensmitteln in Berührung zu kommen.</p> <p>Die GMF-Verordnung gilt für die in Anhang I der Verordnung (EG) 1831/2003 aufgeführten Gruppen und Materialien und Gegenstände oder separaten Materialien und Gegenstände, die in diesen Materialien und Gegenständen verwendet werden, sollen im Einklang im allgemeinen und zusätzlichen Regeln für gute Herstellungspraxis (good manufacturing practice, GMF) gefertigt werden.</p> <p>Es obliegt dem Unternehmer ein wirksames und dokumentiertes Qualitätssicherungssystem festzulegen und anzuwenden.</p> <p>Ebenso hat der Unternehmer ein wirksames Qualitätssicherungssystem festzulegen und anzuwenden.</p>	<p>GMF - Regulation Regulation (EC) 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food.</p> <p>The regulation (EC) 2023/2006 is valid as of 1st August 2009.</p> <p>The GMF regulation is valid for groups of materials and articles listed in annex I to regulation (EC) 1831/2003 and combination of those materials and articles or regulated materials and articles used in those materials and articles should be manufactured in compliance with general and detailed rules on good manufacturing practice (GMP).</p> <p>The business operator shall establish, implement and ensure adherence to an effective and documented quality assurance system.</p> <p>The business operator shall establish and maintain an effective quality control system.</p>
<p>Verordnung (EG) Nr. 1020/11 über Materialien und Gegenstände aus Kunststoff, die dazu bestimmt sind, mit Lebensmitteln in Berührung zu kommen.</p> <p>Die Verordnung (EG) Nr. 1020/11 ist gestützt auf die Verordnung (EG) Nr. 1831/2003.</p> <p>Gemäß Artikel 9 Absatz 1 Buchstabe b der Verordnung (EG) Nr. 1831/2003 sollte die Freisetzung von Stoffen aus Lebensmittelkontaktmaterialien und -Gegenständen keine unvermeidbaren Veränderungen der Zusammensetzung des Lebensmittels herbeiführen.</p> <p>FDA Food and Drug Administration</p> <p>Die FDA ist eine US-Bundesbehörde. Die FDA ist die Lebensmittel-Überwachungs- und Arzneimittelzulassungsbehörde der Vereinigten Staaten und ist dem amerikanischen Gesundheitsministerium unterstellt.</p> <p>CFR - Code of Federal Regulations Title 21</p> <p>Der Titel 21 der CFR ist für Verordnungen der Lebensmittel und Arzneimittel reserviert. Die Online Referenzen werden jährlich aktualisiert. Für die aktuelle Version besuchen Sie die Webseite „Electronic Code of Federal Regulations (eCFR)“.</p>	<p>Regulation (EC) No. 1020/11 on plastic materials and articles intended to come into contact with food.</p> <p>The regulation (EC) No. 1020/11 have regard to regulation (EG) No. 1831/2003.</p> <p>According to article 3 (1) (b) of regulation No. 1831/2003 the release of substances from food contact materials and articles should not bring about unacceptable changes in the composition of the food.</p> <p>FDA Food and Drug Administration</p> <p>The FDA is a US authority. The FDA is responsible for the control of food and certification of drugs in the United States of America. It is subordinated to the Ministry of Health.</p> <p>CFR - Code of Federal Regulations Title 21</p> <p>Title 21 of the CFR is reserved for rules of the Food and Drug Administration.</p> <p>The online reference of CFR Title 21 is updated once a year. For the most up to date version of CFR Title 21, go to the Electronic Code of Federal Regulations (eCFR).</p>
<p>Seite 2 von 3 RECHNER Industrie-Elektronik GmbH - Gaußstraße 6 - 10 - D-68623 Lampertheim - e-mail: info@rechner-sensors.de - www.rechner-sensors.com</p>	

RECHNER SENSORS	
Anhang Nr. 1/ Appendix No. 1	Sprache/Language: English
XXXXXXXX	
<p>Seite 3 von 3 RECHNER Industrie-Elektronik GmbH - Gaußstraße 6 - 10 - D-68623 Lampertheim - e-mail: info@rechner-sensors.de - www.rechner-sensors.com</p>	

On the 3rd page and / or further pages you will find for the material that can be in contact with food detailed information about the material, its origin and characteristics.

CONFORMITY DECLARATION

RECHNER Sensors has a variety of sensors in its product range that are designed according to the criteria for hygienic design and that comply with the Directive 1935/2004.

You can recognize these products by the information on the individual data sheets:

- Suitable for food contact and
- Traceability according to Directive (EC)1935/2004 and
- Food logo and
- FDA-No. with the material specifications



CERTIFICATE OF COMPLIANCE ACCORDING TO EN 10234

On request RECHNER Sensors provides test certificates according to EN 10234 for metallic products:

Certificate of Compliance 2.1

- Confirms the conformity with the order

Certificate of Compliance 2.2

- Confirms the conformity with the order with indication of test results

Inspection Certificate 3.1


- Confirms the conformity with the order with indication of test results

Inspection Certificate 3.2

- Confirms the conformity with the order with indication of test results

INSPECTION CERTIFICATE 3.1 ACCORDING TO EN 10234

Below you see an example of an Inspection certificate 3.1.
If required, please indicate it with your order.



**Abnahmeprüfzeugnis 3.1
nach EN 10204**

**Inspection certificate 3.1
according to EN 10204**

Besteller: / Customer: XXXXXX
 Bestell-Nr.: / Order No.: XXXXXX
 Artikelnr. Besteller: / Article No. Costumer: XXXXXX

Auftragsnr.: / Order No.: XXXXXX
 Artikel Nr. / Article No.: XXXXXX
 Artikelname: / Article name: XXXXXX
 Serien-Nr.: / Serial No.: XXX/XXXXXX

• Hiermit bestätigen wir, dass die gelieferten Erzeugnisse, die in der Bestellung festgelegten Anforderungen erfüllen.

• We declare herewith, that the products supplied are in compliance with the requirements of the order.

Artikel-Nr. / Article-No.	Serien-Nr. / Serial No.	Prüfdatum / Testing date	Bemerkungen / Comment
XXXXXX	XXXXXX	XXXXXX	-
XXXXXX	XXXXXX	XXXXXX	-
XXXXXX	XXXXXX	XXXXXX	-
XXXXXX	XXXXXX	XXXXXX	-

Hiermit bestätigen wir, dass die Prüfeinheit und die Durchführung der Erzeugnisse die in der Erzeugnis Spezifikation, den amtlichen Vorschriften und Technischen Regeln und / oder der Bestellung festgelegt sind, angewendet wurden, die getesteten Erzeugnisse sind Bestandteil der gelieferten Erzeugnisse.

• Alle Prüfunterlagen werden über einen Zeitraum von mindestens 10 Jahren aufbewahrt. Eine Überprüfung der Dokumente durch den Besteller ist zu jeder Zeit möglich.

We declare herewith, that the test unit and the tests to be carried out are defined by the product specification, the official regulation and corresponding rules and / or the order. The tested products are part of the products that have been delivered.

• All test reports are kept for a time period of 10 years. A review of the test documents by the customer is possible at any time.

Lampertheim, 13.07.2020
 Name des Abnahmebeauftragten /
 Name of inspection representative: _____
 Unterschrift / Signature: _____

RECHNER Industrie-Elektronik GmbH • Gaußstraße 6 – 10 • D-68623 Lampertheim • e-mail: info@rechner-sensors.de • www.rechner-sensors.com

TRI-CLAMP & TRI-CLOVER

TRI-CLAMP OR TRI-CLOVER:

TWO DIFFERENT NAMES FOR
THE SAME SYSTEM.

TRI-CLAMP & TRI-CLOVER

SENSORS WITH TRI-CLAMP / TRI-CLOVER - THE SIMPLE CONNECTION THAT GUARANTEES ASEPTIC QUALITY.

National and International guidelines for the food, pharmaceutical and biochemical industries place high demands on manufacturers and therefore also on the machines and plant manufacturers in these industries

THE PURITY AND STERILITY OF THE PRODUCTS AND THUS CONSUMER PROTECTION HAVE TOP PRIORITY.

Plants and machinery must be manufactured with the understanding that all parts which could come into contact with food or pharmaceutical products must be easy as well as safe to clean. Tri-Clamp pipe connections (also known as Tri-Clover) have been established in these markets for many years.

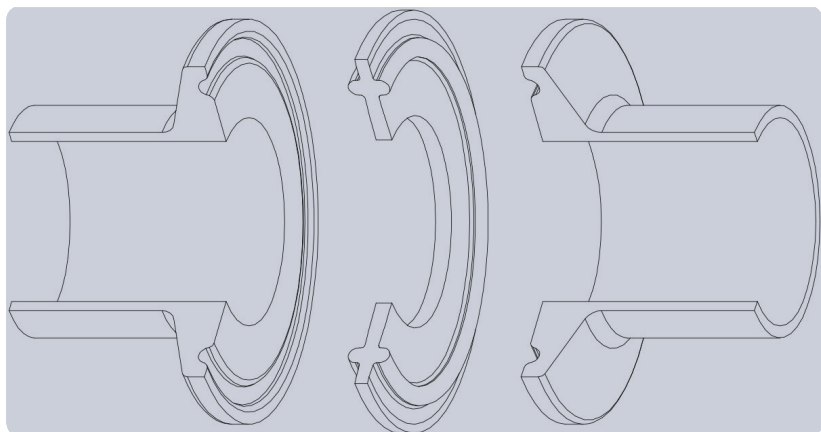
TRI-CLAMP PIPE CONNECTIONS AND PROCESS CONNECTIONS ARE USED TO PRODUCE ASEPTIC CONNECTIONS, WITHOUT DEAD SPACES AND AIR INGRESS. THIS PREVENTS POLLUTION AND CROSS-CONTAMINATION.

The Tri-clamp system, in combination with the selected food-grade material used, coupled with corresponding high surface finishes, are perfectly qualified for CIP and SIP and this explains the success.

The Tri-Clamp system consists of two identical fittings, which are clamped together with a clamp and wing screw. Between them there is an accurately matching gasket, which is of course inert, and it is also suitable for food contact. Commonly used materials for the seals are EPDM, Teflon and Viton.

Tri-Clamps therefore offer the particular advantage that assembly and disassembly can be carried out without tools. If all parts are manufactured in accordance with standards and the correct seal and clamp are selected, then there is practically no risk of making mistakes.

2 SYMMETRICAL PARTS AND
AN EXACT FITTING GASKET
IN BETWEEN



Tri-Clamp / Tri-Clover is globally proven, known and used.

THANKS TO THE STANDARDISATION THROUGH INTERNATIONAL NORMS, SUCH AS BS, DIN, ISO, A LARGE NUMBER OF ASEPTICALLY DESIGNED COMPONENTS ARE EASILY AVAILABLE TO THE USER WORLDWIDE.

Throughout the food, pharmaceutical and biochemical industries, fill levels in the dosing and storage containers must be measured in the various processes. It is therefore essential that we equip our sensors and level measurement systems with preferred Tri-Clamp process connection formats and options.

RECHNER Sensors offers many sensors with the Tri-Clamp facility.

WE USE HIGH QUALITY STAINLESS STEEL (AISI 316L) WITH A SURFACE QUALITY Ra OF 0.4 MM PLUS PLASTICS WHICH ARE SUITABLE INDUSTRY APPROVED PTFE OR PEEK.

These materials are inert and have excellent properties in terms of chemical resistance.

Furthermore we also offer adapters, to simplify the conversion of G $\frac{1}{2}$ " or G1" thread devices for a Tri-Clamp set-up. It is up to the customer to decide whether they wish to work with sensors + adapters or to reduce the number of connection points and select a sensor with an integral Tri-Clamp connection.

IMPORTANT FOR TRI-CLAMP / TRI-CLOVER MOUNTING:

DO THE TWO TRI-CLAMP MODULES FIT?
ARE THEY DEFECT-FREE? (NO DAMAGE)
DOES THE GASKET FIT THE TWO TRI-CLAMP PARTS?
IS THE GASKET DEFECT-FREE? (NO DAMAGE)?
IS IT THE CORRECT CLAMP? (NOT TOO WIDE + NOT A TIGHT FIT)

IF ALL THE PARTS ARE CORRECTLY ASSEMBLED, THEN THE CLAMP WITH THE WING SCREW, WILL SEAL WHEN JUST HAND TIGHTENED. DO NOT OVER-TIGHTEN TO ENSURE THAT THE GASKET IS NOT DAMAGED.

IF THE GASKET IS DAMAGED, THERE IS A RISK OF CONTAMINATION.

Tri-Clamp

Easy

Securely

**Quick connection or disconnection for:
Cleaning
maintenance or
reconfiguration**

TRI-CLAMP / TRI-CLOVER:

THE SIMPLE CONNECTION FOR
BETTER FOOD SAFETY.

PROTECTS PRODUCT
SUSTAINABILITY.

■ **TRI-CLAMP THE PREFERRED CONNECTION:**

- Beverage industry (e.g. Milk, Wine, Juice, Beer)
- Breweries
- Distilleries
- Food Industry
- Cosmetic Industry
- Chemical Industry
- Pharmaceutical Industry
- Biochemical Industry

■ **Tri-Clamp DIN 32676 is:**

- Symmetrical - both connection parts are identical
- Simple to assembly without tools
- Dead space free
- Easy to seal
- Aseptic, easy and safe to clean
- CIP and SIP and ensures compliance with the highest hygienic requirements
- Internationally well accepted and readily available

DN 20, DN25, DN32, DN 40, DN50

OUR SENSORS AND ADAPTORS CORRESPOND TO DIN 32676 ROW A.
PLEASE SEE THE SPECIFICATION SHEET OF THE SENSOR OR ADAPTER
FOR THE DIMENSION.

OTHER TRI-CLAMP PROCESS CONNECTIONS ARE AVAILABLE ON
REQUEST.



TRI-CLAMP & TRI-CLOVER





FOOD CONTACT MATERIALS

FOOD CONTACT MATERIALS

DEPENDING ON
THE APPLICATION,

FOOD CONTACT
MATERIALS

CAN BE:
SENSOR BODIES
MADE OF PLASTIC,
CERAMIC OR
METAL

SEALS

CABLE

RECHNER SENSORS HAS A BROAD RANGE OF SENSORS WHERE THE HOUSINGS ARE DESIGNED TO COMPLY WITH THE VALID REGULATIONS FOR FOOD CONTACT.

According to

Artikel 16 of Regulation 1935/2004

manufacturer of products and materials which may come into contact with food and for which **specific measures** are prescribed must attach a written declaration confirming that the food contact materials comply with the rules applicable to them.

At annex I of the Regulation 1935/2004 contains a list of groups of materials and articles which may be covered by specific measures:

1. Active and intelligent materials and articles
2. Adhesives
3. Ceramics
4. Cork
5. Rubbers
6. Glass
7. Ion-exchange resins
8. Metaals and alloys
9. Paper and board
10. Plastics
11. Printing inks
12. Regenerated cellulose
13. Silikones
14. Textiles
15. Varnishes and coatings
16. Waxes
17. Wood

FOOD CONTACT MATERIALS

WHICH PARTS OF SENSORS ARE FOOD CONTACT MATERIALS?

This depends on the installation situation, whether sensors are used for flush or non-flush installation.

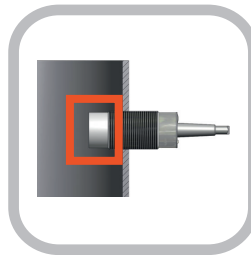
FLUSH MOUNTING:

In this case, usually only the active surface (front surface) is in contact with the food, as the sensor is installed flush with the container wall and does not project into the container.



NON-FLUSH MOUNTING:

In this case, the active surface of the sensor is usually in contact with the food (front surface including lateral housing parts), since the sensor is not flush with the container wall and thus projects into the container.



Depending on the application, a sensor in a completely plastic housing is preferable, where the part in contact with the food is made from a single part.

With the combination of metal housing / active surface made of plastic, there are junctions which can provide space for deposits and/or micro-organisms. In addition, there are adhesive areas that may have to be considered when designing the housing for food contact.

Mounting with welding sockets can optimize the installation. Tri-Clamp is also proven solution here.

No rule without exception - sensor completely in contact with food:

If the application requires that all parts of the sensor must be in contact with food, then all parts of the sensor must be checked for suitability. Complete housing with lid, cable or connector.

The rear of the sensor with cable outlet and LED, potentiometer entry, etc. can easily be converted to food contact suitability with a sealing kit. Suitable cables and connectors are also available.

FOOD CONTACT MATERIALS

ADVANTAGE:
PLASTIC HOUSING
MADE FROM ONE PART

NONE MATERIAL JOINTS

NO CREVICES

ASSEMBLY WITH
WELDING SOCKETS OR
TRI-CLAMP ARE
WELL-TRIED

FOOD CONTACT MATERIALS

PLASTICS

RECHNER Sensors uses the following plastic materials for the sensor bodies:

Depending on the application, different requirements regarding surface quality, chemical resistance, temperature resistance, pressure resistance must be taken into account.

Abbreviation	Material	FDA -No.	Surface quality Ra	Food contact permitted*	Max. ambient temperature*	Pressure typ. max.*	Chemical resistance*	Traceability according to EC 1935/2004*
PC	Polycarbonate	FDA 21 CFR 177.1580	≤ 0,8 µm	Yes	N. A.	N. A.	N.A.	N.A.
PEEK FG	Polyetheretherketone FG	FDA 21 CFR 177.2415	≤ 0,8 µm	Yes	250°C	10 bar	Good	Yes
POM FG	Polyoxymethylene FG	FDA 21 CFR 177.2470	≤ 0,8 µm	Yes	N.A.	N.A.	N.A.	N.A.
PTFE	Polytetrafluorethylene	FDA 21 CFR 177.1550	≤ 1,6 µm	Yes	250°C	3 bar	Very good	Yes
PVDF	Polyvinylidenfluoride	FDA 21 CFR 177.2510	≤ 0,8 µm	Yes	140°C	N.A.	Good	N.A.

* Please refer to the specific data on the sensor data sheet. The data on the data sheet have priority (N.A. = Data on request)

Housing materials

The application of the housing materials used is based on the technical specifications of the material and of the manufacturer. Even though RECHNER Sensors have far-reaching application experience concerning the use of different housing materials, the customer is responsible for checking in each case that the housing material is suitable for the application.

FOOD CONTACT MATERIALS

METALS

RECHNER Sensors uses the following metals for the sensor bodies

Depending on the application, different requirements regarding surface quality, chemical resistance, temperature resistance, pressure resistance must be taken into account.

Abbreviation	Material	FDA - No.	Surface quality Ra	Food contact permitted*	Max. ambient temperature*	Chemical resistance*	Traceability according to EC 1935/2004*
VAa	Stainless steel VA, Material No. 1.4301 (AISI 304)	No	≤ 0,8 µm	Yes	N. A.	Rust resistant	N.A.
VAb	Stainless steel VA, Material No. 1.4305 (AISI 303)	No	≤ 0,8 µm	Yes	N.A.	Rust resistant	N.A.
VAc	Stainless steel VA, Material No. 1.4494 (AISI 316L)	FDA conform	≤ 0,8 µm	Yes	N.A.	Rust and acid resistant	Yes

* Please refer to the specific data on the sensor data sheet. The data on the data sheet have priority (N.A. = Data on request)

Housing materials

The application of the housing materials used is based on the technical specifications of the material and of the manufacturer. Even though RECHNER Sensors have far-reaching application experience concerning the use of different housing materials, the customer is responsible for checking in each case that the housing material is suitable for the application.

Kundennähe ist uns wichtig!

Rechner Sensors hat Tochter- und Schwesterfirmen in China, Großbritannien, Italien, Kanada, Südkorea und in den Vereinigten Staaten von Amerika.

Darüber hinaus haben wir Vertretungen in mehr als 50 Ländern. Die Adressen unserer Handelspartner finden Sie auf unserer Internetseite unter der Rubrik Kontakt.

Customer proximity guaranteed!

Rechner Sensors has daughter and sister companies in China, Great Britain, Italy, Canada, South Korea and in the U.S..

Furthermore we have representative offices in over 50 countries. For the addresses of our sales partners please visit our website. You will find the addresses under the category contact.

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