Herstelleraussage

14278480.05

Materialien für den Einsatz in Kontakt mit Lebensmitteln

Wir bestätigen hiermit für die Materialien u. Gegenstände, die bei bestimmungsgemäßem Gebrauch in Kontakt mit Lebensmitteln kommen können, die Konformität der metallischen messstoffberührten Materialien mit den Anforderungen der

GB 4806.1-2016 Nationaler Lebensmittelsicherheitsstandard: Allgemeine Sicherheitsanforderungen an Materialien, die mit Lebensmitteln in Berührung kommen.

Dies gilt für folgende Typen:

Druckmittler mit Sterilanschluss für die sterile Verfahrenstechnik

981.18, 990.17, 990.18, 990.19, 990.20, 990.21, 990.22, 990.24, 990.30, 990.50, 990.51, 990.52, 990.53, 990.60, SA-11, DSS18T, DSS19T, DSS22T, DMS-FP, DMSU21SA, DSSA11SA

Alle messstoffberührten Teile sind aus:

1.4435 (316L), Hastelloy C22 (2.4602 / N06022) / C276 (2.4819 / N10276), Inconel 718 (2.4668 / N07718)

Die eingesetzten Werkstoffe wurden nach **GB 4806.9-2023** getestet und halten die zulässigen Migrationsgrenzwerte ein.

Der Fertigungsprozess der Geräte erfolgte nach "Guter Herstellungspraxis", wie in **GB 31603-2015 Nationaler Lebensmittelsicherheitsstandard: Allgemeine Hygienevorschriften für die Herstellung von Materialien, die mit Lebensmitteln in Berührung kommen, und deren Produkten** beschrieben.

Migrationstest durchgeführt von Intertek Testing Services Shenzhen Ltd., Shenzhen, China - Testreport WOHK21008-A.

Manufacturer Statement

14278480.05

Food Contact Materials

For the materials and articles which may come into contact with food when used as intended, we hereby confim the conformity of the wetted metal materials with the requirements of

GB 4806.1-2016 National Food Safety Standard: General Safety Requirements on Food Contact Materials.

This applies to the following models:

Diaphragm seal with sterile connection for sanitary applications

981.18, 990.17, 990.18, 990.19, 990.20, 990.21, 990.22, 990.24, 990.30, 990.50, 990.51, 990.52, 990.53, 990.60, SA-11, DSS18T, DSS19T, DSS22T, DMS-FP, DMSU21SA, DSSA11SA

All wetted parts are made of:

1.4435 (316L), Hastelloy C22 (2.4602 / N06022) / C276 (2.4819 / N10276), Inconel 718 (2.4668 / N07718)

The materials used were tested according to **GB 4806.9-2023** and comply to the permissible migration limits.

The manufacturing process has followed „Good Manufacturing Practice" as specified in **GB 31603-2015 National Food Safety Standard: General Hygienic Practice for Production of Food Contact Materials and Its Products**.

Migration testing performed by Intertek Testing Services Shenzhen Ltd., Shenzhen, China - test report WOHK21008-A.

Unterzeichnet für und im Namen von / Signed for and on behalf of

WIKA Alexander Wiegand SE & Co. KG

Klingenberg, 2026-07-14

i. V.

Matthias Kirch, Vice President
Global Business Unit Pressure

Andreas Massong, Head of Quality Assurance
Global Business Unit Pressure

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Kommanditgesellschaft: Sitz Klingenberg –
Amtsgericht Aschaffenburg HRA 1819

Komplementärin:
WIKA International SE - Sitz Klingenberg -
Amtsgericht Aschaffenburg HRB 10505
Vorstand: Alexander Wiegand
Vorsitzender des Aufsichtsrats: Prof. Dr. Roderich C. Thümmel

Herstellererklärung

Dokument Nr.:

14315607.06

Wir bestätigen hiermit für die Materialien und Gegenstände, die bei bestimmungsgemäßem Gebrauch in Kontakt mit Lebensmitteln kommen können, die Konformität mit den allgemeinen Anforderungen der

Verordnung (EG) Nr. 1935/2004 vom 27. Oktober 2004 über Materialien und Gegenstände, die dazu bestimmt sind, mit Lebensmitteln in Berührung zu kommen.

Druckmittler(-systeme) für die sterile Verfahrenstechnik:

Typ	Verfügbares Material
990.17 bis 990.22, 990.24, 990.50 bis 990.53, 990.60, 981.18 bis 981.22, 981.50, 981.51 bis 981.53, DMSU21SA, DSSA11SA	Edelstahl CrNi-Stahl 1.4435 (316L) optional: 2.4602 (C22) 2.4819 (C276)
990.30	Edelstahl CrNi-Stahl <= PN600 1.4435 (316L) >PN600 1.4571 (316Ti) / 1.4542 (630)
DSS18F, DSS18T, DSS19F, DSS19T, DSS22F, DSS22P, DSS22T, SA-11, DMS-FP, PEU-21	Edelstahl CrNi-Stahl 1.4435 (316L)

Adaptersysteme für die sterile Verfahrenstechnik:

Typ	Verfügbares Material
910.60, 910.61	Edelstahl CrNi-Stahl 1.4435 (316L)

Alle medienberührten Bauteile sind aus:
siehe Tabellen oben

Die Eignung zum Einsatz, sowie die geeignete Reinigung und Wartung, ist bezogen auf die Applikation vom Anwender sicherzustellen.

Die Fertigungsprozesse der Geräte wurde nach “Guter Herstellungspraxis“, wie in der Verordnung (EG) Nr. 2023/2006 „über gute Herstellungspraxis für Materialien und Gegenstände, die dazu bestimmt sind, mit Lebensmitteln in Berührung zu kommen“ vom 22. Dezember 2006 beschrieben, durchgeführt.

Unterzeichnet für und im Namen von / *Signed for and on behalf of*

WIKA Alexander Wiegand SE & Co. KG

Klingenberg, 2025-11-11

i.V.

Matthias Kirch, Vice President
Center of Excellence Pressure

Declaration of Manufacturer

Document No.:

14315607.06

For the materials and article which may come into contact with food when used as intended, we hereby confirm the conformity with the regular requirements of

Regulation (EC) No. 1935/2004 of October 27, 2004 on materials and articles intended to come into contact with food.

Diaphragm Seal (Systems) for sanitary applications:

Type	available material
990.17 bis 990.22, 990.24, 990.50 bis 990.53, 990.60, 981.18 bis 981.22, 981.50, 981.51 bis 981.53, DMSU21SA, DSSA11SA	Stainless steel 1.4435 (316L) optional: 2.4602 (C22) 2.4819 (C276)
990.30	Stainless steel <= PN600 1.4435 (316L) >PN600 1.4571 (316Ti) / 1.4542 (630)
DSS18F, DSS18T, DSS19F, DSS19T, DSS22F, DSS22P, DSS22T, SA-11, DMS-FP, PEU-21	Stainless steel 1.4435 (316L)

Adapter Systems for sanitary applications:

Type	available material
910.60, 910.61	Stainless steel 1.4435 (316L)

All wetted parts are made of:
See tables above

Based on the specific application, the suitability for use as well as the proper cleaning and maintenance has to be ensured by the user.

The manufacturing process has followed „Good Manufacturing Practice (GMP)” as specified in the regulation (EC) No 2023/2006 “on good manufacturing practice for materials and articles intended to come into contact with food” of 22. December 2006.

Andreas Massong, Head of Quality Assurance
Center of Excellence Pressure

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Amtsgericht Aschaffenburg HRA 1819

Komplementärin:
WIKA International SE - Sitz Klingenberg -
Amtsgericht Aschaffenburg HRB 10505
Vorstand: Alexander Wiegand
Vorsitzender des Aufsichtsrats: Prof. Dr. Roderich C. Thümmel

Herstelleraussage

14397576.03

Wir erklären in alleiniger Verantwortung, dass die folgenden Produkte

Typ:

981.18	990.19	DSS18F
981.19	990.20	DSS18T
981.20	990.21	DSS19F
981.21	990.22	DSS19T
981.22	990.24	DSS22F
981.50	990.30	DSS22P
981.51	990.50	DSS22T
981.52	990.51	DMS-FP
981.53	990.52	DMSU21SA
990.17	990.53	DSSA11SA
990.18	990.60	

Gemäß gültigem Datenblatt:

DS95.04	DS95.20	DS99.40
DS95.05	DS98.40	DS99.41
DS95.06	DS98.50	DS99.49
DS95.07	DS98.51	DS99.50
DS95.08	DS98.52	DS99.51
DS95.21	DS99.33	DS99.55
DS95.22	DS99.39	DS95.11
		DS99.25

mit den nachfolgend aufgeführten Druck-übertragungsflüssigkeiten ausgeführt werden können *(FDA 21 CFR)*:

A-Nr. 0664804 / KN7	*(§182.1320)*
A-Nr. 1490451 / KN59	*(§172.856; §174.5)*
A-Nr. 11314915 / KN92	*(§172.878; §178.3620(a))*

Die Druckübertragungsflüssigkeiten werden mit einer FDA Anforderung bei den jeweiligen Vorlieferanten bezogen.

Manufacturer Statement

14397576.03

We declare under our sole responsibility, that the following products

Model:

981.18	990.19	DSS18F
981.19	990.20	DSS18T
981.20	990.21	DSS19F
981.21	990.22	DSS19T
981.22	990.24	DSS22F
981.50	990.30	DSS22P
981.51	990.50	DSS22T
981.52	990.51	DMS-FP
981.53	990.52	DMSU21SA
990.17	990.53	DSSA11SA
990.18	990.60	

According to the valid data sheet:

DS95.04	DS95.20	DS99.40
DS95.05	DS98.40	DS99.41
DS95.06	DS98.50	DS99.49
DS95.07	DS98.51	DS99.50
DS95.08	DS98.52	DS99.51
DS95.21	DS99.33	DS99.55
DS95.22	DS99.39	DS95.11
		DS99.25

can be manufactured with diaphram seal fill fluids listed below *(FDA 21 CFR)*:

P-No. 0664804 / KN7	*(§182.1320)*
P-No. 1490451 / KN59	*(§172.856; §174.5)*
P-No. 11314915 / KN92	*(§172.878; §178.3620(a))*

The fluids will be purchased and delivered regarding the FDA requirements.

Unterzeichnet für und im Namen von / Signed for and on behalf of

WIKA Alexander Wiegand SE & Co. KG

Klingenberg, 16.06.2023

Geschäftsbereich / Process Instrumentation Pressure
Company Division / Process Instrumentation Pressure

i.V.

Matthias Kirch

Qualitätsmanagement / Process Instrumentation Pressure
Quality management / Process Instrumentation Pressure

i.A.

Roland Stapf

Unterschrift autorisiert durch das Unternehmen / Signature authorized by the company

Manufacturer Statement

14682890.01

Safe failure fraction (SFF) details for

Diaphragm Seals and built on components

This manufacturer statement summarizes the safe failure fraction (SFF) within the scope of functional safety for WIKA mechanical component in accordance with IEC 61508 and under the specified condition in product operational instruction and datasheet.

In general, for a complete evaluation of a system, all requirements of IEC 61508 must be considered for all components used in the system. Please note that the individual failure rates for each component must be added up to get the overall failure rate of the entire system.

The tables listed in the appendix apply to the failure rates in accordance with IEC 61508 for the worst-case configurations of the following variants (Failure rates based on exida Report No.: WIKA 10/03-056 R003):

Reference tables in appendix *	Diaphragm Seals and built on components
DS01	990.15; 990.18; 990.19; 990.20; 990.21; 990.22; 990.24; 990.30; 990.37; 990.50; 990.51; 990.52; 990.53; 990.60
DS02	990.27
DS03	990.28; 990.29; 990.35; 990.48; 990.49
DS04	990.26
DS05	990.10; 990.12; 990.14; 990.16; 990.34; 990.40; 990.41
DS06	990.36
DS01+AD05**	DMS27; DMSFP
DS05+AD05**	DMS34
IS01	981.10; 981.18; 981.19; 981.20; 981.21; 981.22; 981.27; 981.50; 981.51; 981.52; 981.53
AD01	Cooling tower, welding adapter, capillary, threaded connector

** For safety applications only the described configurations of the Diaphragm Seals have been considered. All other possible variants and configurations are not covered.*
*** Please note the total failure rate has to be calculated from the tables below.*

Signed for and on behalf of

WIKA Alexander Wiegand SE & Co. KG

Klingenberg, 2024-02-23

CoE Pressure

i.V.

Matthias Kirch

Quality management / CoE Pressure

i. A.

Roland Stapf

Appendix - Failure rates for WIKA Diaphragm Seals and built on components

The Diaphragm Seals and built on components are classified as a device that is part of a Type A' element according to IEC 61508, having a hardware fault tolerance of 0.

The Diaphragm Seal can be classified as a 2H device when the listed failure rates are used. When 2H data is used for all of the devices in an element, then the element meets the hardware architectural constraints up to SIL 2 at HFT=0 (or SIL 3 @ HFT=1) per Route 2H. If Route 2H is not applicable for the entire final element, thel architectural constraints will need to be evaluated per Route 1_H.

The failure rates listed below are based an over 350 billion-unit operating hours of process industry field failure data. The failure rate predictions reflect realistic failures and include site specific failures due to human events for the specified Site Safety Index (SSI).

Example system calculation

The following table shows the results of typical system configuration as example:

	Profile 3	
	Normal service	**Severe service**
Fail Safe (λ_{safe})	**0 FIT**	**0 FIT**
Fail Dangerous ($\lambda_{dangerous}$)	**21 FIT + 23 FIT = 44 FIT**	**51 FIT + 23 FIT = 74 FIT**
No effect	0 FIT + 3 FIT = 3 FIT	0 FIT + 3 FIT = 3 FIT
External leakage	0 FIT	0 FIT
Total failure rate (safety function)	**44 FIT**	**74 FIT**

Failure rate tables

The following tables show the failure rates per IEC 61508 for the worst-case configurations of the considered variants.

Table 3: DS01 - Diaphragm seal, flanged or front flush

	Profile 3	
	Normal service	**Severe service**
Fail Safe (λ_{safe})	**0 FIT**	**0 FIT**
Fail Dangerous ($\lambda_{dangerous}$)	**21 FIT**	**51 FIT**
No effect	0 FIT	0 FIT
External leakage	0 FIT	0 FIT
Total failure rate (safety function)	**21 FIT**	**51 FIT**

Table 4: DS02 - Diaphragm Seal, flanged or front flush, with insert of special material

	Profile 3	
	Normal service	**Severe service**
Fail Safe (λ_{safe})	**0 FIT**	**0 FIT**
Fail Dangerous ($\lambda_{dangerous}$)	**44 FIT**	**74 FIT**
No effect	2 FIT	2 FIT
External leakage	0 FIT	0 FIT
Total failure rate (safety function)	**44 FIT**	**74 FIT**

Table 5: DS03 - Diaphragm Seal - with extended diaphragm and for vacuum applications

	Profile 3	
	Normal service	**Severe service**
Fail Safe (λ_{safe})	**0 FIT**	**0 FIT**
Fail Dangerous ($\lambda_{dangerous}$)	**65 FIT**	**95 FIT**
No effect	9 FIT	9 FIT
External leakage	15 FIT	15 FIT
Total failure rate (safety function)	**65 FIT**	**95 FIT**

Table 6: DS04 - Diaphragm seal with internal diaphragm

	Profile 3	
	Normal service	**Severe service**
Fail Safe (λ_{safe})	**0 FIT**	**0 FIT**
Fail Dangerous ($\lambda_{dangerous}$)	**26 FIT**	**56 FIT**
No effect	0 FIT	0 FIT
External leakage	0 FIT	0 FIT
Total failure rate (safety function)	**26 FIT**	**56 FIT**

Table 7: DS05 - Diaphragm Seal with internal diaphragm and threaded connection

	Profile 3	
	Normal service	Severe service
Fail Safe (λ_{safe})	**0 FIT**	**0 FIT**
Fail Dangerous ($\lambda_{dangerous}$)	**21 FIT**	**51 FIT**
No effect	26 FIT	26 FIT
External leakage	61 FIT	61 FIT
Total failure rate (safety function)	**21 FIT**	**51 FIT**

Table 8: DS06 - Diaphragm Seal - with plate for abrasive media

	Profile 3
	Severe service
Fail Safe (λ_{safe})	**0 FIT**
Fail Dangerous ($\lambda_{dangerous}$)	**100 FIT**
No effect	0 FIT
External leakage	0 FIT
Total failure rate (safety function)	**100 FIT**

Table 9: IS01 - In-line Diaphragm Seal

	Profile 3	
	Normal service	Severe service
Fail Safe (λ_{safe})	**0 FIT**	**0 FIT**
Fail Dangerous ($\lambda_{dangerous}$)	**45 FIT**	**75 FIT**
No effect	1 FIT	1 FIT
External leakage	0 FIT	0 FIT
Total failure rate (safety function)	**45 FIT**	**75 FIT**

Table 10: AD01 - Cooling tower, welding adapter, capillary, threaded connector

	Profile 3
	Normal service
Fail Safe (λ_{safe})	**0 FIT**
Fail Dangerous ($\lambda_{dangerous}$)	**23 FIT**
No effect	3 FIT
External leakage	0 FIT
Total failure rate (safety function)	**23 FIT**

Table 11: AD05 - diaphragm break monitoring system

	Profile 3
	Normal service
Fail Safe (λ_{safe})	**0 FIT**
Fail Dangerous Detected (λ_{DD})	**33 FIT**
Fail Dangerous Detected (λ_{dd})	10 FIT
Fail Annunciation Detected (λ_{AD})	23 FIT
Fail Dangerous Undetected (λ_{DU})	**1 FIT**
Fail Annunciation Undetected (λ_{AU})	3 FIT
No effect	3 FIT
External leakage	0 FIT
Total failure rate (safety function)	**34 FIT**

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Kommanditgesellschaft: Sitz Klingenberg
Amtsgericht Aschaffenburg HRA 1819

Komplementärin:
WIKA International SE - Sitz Klingenberg -
Amtsgericht Aschaffenburg HRB 10505
Vorstand: Alexander Wiegand
Vorsitzender des Aufsichtsrats: Prof. Dr. Roderich C. Thümmel

Herstelleraussage

Dokument Nr.: 14756019.01

Wir als Hersteller bestätigen für unsere folgend genannte Produkte,

Druckmittlersystem für maximal zulässigen Druck (PS) < 200 bar

gemäß den gültigen Datenblättern

WIKA model	Data sheet	WIKA model	Data sheet	WIKA model	Data sheet
DMS34	DS 95.18	DSS22P	DS 95.07	DSS18T	DS 95.05
DMS27	DS 95.26	DSS19F	DS 95.21	DSS10T	DS 95.02
DMS-FP	DS 95.21	DSS18F	DS 95.04	DSS19T	DS 95.22
Hydra-Gauge	SP 99.20	DSS10M	DS 95.01	DSS34T	DS 95.16
Hydra-Sensor	SP 99.21	DSS34M	DS 95.15	DSS27T	DS 95.13
DSS22F	DS 95.06	DSS27M	DS 95.12	DSS26T	DS 95.10
DSS22T	DS 95.08	DSS26M	DS 95.09		

dass diese mit der Richtlinie übereinstimmen und entsprechend geltender guter Ingenieur-praxis ausgelegt und gefertigt werden.

Die Einstufung erfolgt nach
2014/68/EU – Artikel 4, Absatz 3

Die Produkte dürfen bezüglich der oben genannten Richtlinie nicht mit CE gekennzeichnet werden.

Manufacturer's Statement

Document No.: 14756019.01

We as manufacturer of the below listed products,

diaphragm seal system for maximum allowable pressure (PS) < 200 bar

according to the current data sheets

correspond with the directive and were designed and produced in accordance with sound engineering practice.

The classification is based on:
2014/68/EU – article 4, section 3

Regarding the above directive the products may not be marked with CE.

Unterzeichnet für und im Namen von: / Signed for and on behalf of:

WIKA Alexander Wiegand SE & Co. KG
Klingenberg, 2025-02-27

i. V.

Matthias Kirch, Vice President
Center of Excellence Pressure

Andreas Massong, Head of Quality Assurance
Center of Excellence Pressure

Unterschrift autorisiert durch das Unternehmen / Signature authorized by the company