

# Overensstemmelseserklæring Declaration of Conformity

Company **Endress+Hauser A/S, Poppelgårdvej 10-12, 2860 Søborg**

erklærer som eneansvarlig, at instrumenterne  
*declares under sole responsibility, that the instruments*

Product

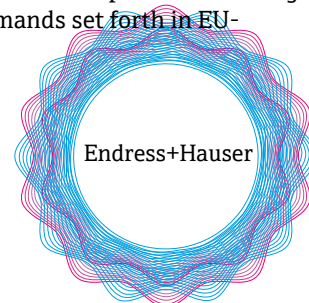
- Cerabar T PMP13x/PMP23
- Ceraphant T PTP3x
- Cerabar M PMP/PMC5x, PMP4x
- Cerabar S PMP/PMC7x
- Deltabar S FMD7x
- Deltapilot M/S FMB5x, FMB7x
- Levelflex FMP52, FMP53
- Levelflex M FMP41C, FMP43
- Liquicap M FMI5x,
- Solicap FTI5x
- Liquiphant M FTL5x(H)
- Liquiphant FTL33
- Liquipoint FTW23/33
- Micropilot M FMR245
- Micropilot FMR 52/62
- Prosonic S FDU91F
- Soliphant M FTM 50/51/52
- Nivector FTI26
- ISFET CPS77D
- T-Mass T
- Promass A, E, I, F, Q, S, P & K
- Promag 10H, 23H & H10
- Promag 50/53/55H
- Promag 5HxB
- Omnigrad TR 44/45/47/48
- Easytemp TMR 35, TM311
- iTherm TM40x, TM41x
- iTherm TrustSens TM37x
- Thermophant T TTR35
- Flowphant T DTT35
- Dosimag 5BH
- Dosimass 8BE
- Unifit CPA442, CPA842 & CPA875
- Indumax CLS/16/54/82(D)
- Smartec CLD18/134
- Tophit CPS441/(D)/471/(D)/171(D)
- Oxygen sensor COS81D
- OUSAF11

med en af følgende hygiejniske procestilslutninger  
*with one of the following hygienic process connections*

- DIN 11851
- DIN 11864
- ISO Clamp 2852
- Triclamp
- SMS
- Varivent
- APV
- Universal process adapter
- Welding nipple (Promag)

med aktivt tilvalg af tilgængelige relevante optioner, kan leveres med godkendelse i.h.t. 3A, 74-06 og/eller i.h.t. EHEDG og/eller i.h.t. kravene i EU-forordning 1935/2004.

with an active selection of available relevant options, can be supplied with compliance according to 3A, 74-06 and/or according to EHEDG and/or according to the demands set forth in EU-declaration 1935/2004.



Instrumenter leveres i overensstemmelse med følgende europæiske forordninger:  
*Instruments are in conformity with the following European Regulations:*

Forordning (EU) nr 1935/2004, om materialer og genstande bestemt til at komme i berøring med fødevarer, artikel 3, 5, 15 og 17.  
*Regulation (EC) No. 1935/2004, on materials and articles intended to come into contact with food, article 3, 5, 15 and 17.*

Forordning (EU) nr 2023/2006 om god fremstillingsmæssig praksis for materialer og genstande bestemt til at komme i berøring med fødevarer.  
*Regulation (EC) No. 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food.*

Forordning (EU) 10/2011 om plastmaterialer og -genstande bestemt til at komme i berøring med fødevarer. For anvendelse i henhold til produktspecifikationer, er de overordnede migrationsgrænser under de, i forordningen, angivne grænseværdier.  
*Regulation (EC) 10/2011 on plastic materials and articles intended to come into contact with food. For use in accordance with product specifications, the overall and specific migration limits are below the regulatory requirements.*

De herefter listede komponenter/materialer med nævnte begrænsninger kan findes anvendt i ovennævnte instrumenter  
*Following substances with limits and /or specification can be used in the above-named products:*

PPVE SML = 0,05mg/kg PLM; - TFE SML = 0,05 mg/kg PLM;

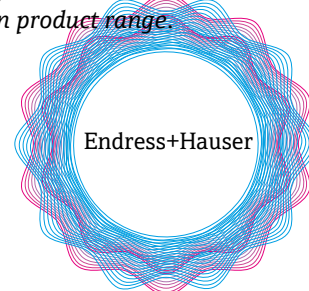
Specifikke materialer i henhold til forordning 10/2011 er under grænseværdierne.  
*Specific materials as per regulation (EU) 10/2011 are below the limits.*

Specifikationer for tiltænkt anvendelse samt begrænsninger:  
*Specifications for intended use or limitations:*

*Type of food or procedures the material is suitable for:*  
*Aqueous, acidic, alcoholic, lacteal, fatty and oily food*

*Duration and temperature of treatment and storage for contact with food:*  
*Short term contact up to 24 h, TM = -40 °C ... +150 °C*

*Relation of surface in contact with food and volume, the conformity of the material or articles is based upon: - For each component different, hence consideration on product range.*

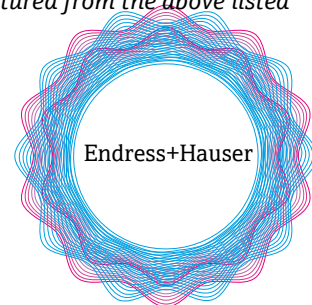


Overensstemmelsen er gældende for materialer i følgende komponenter:  
*This declaration of conformity is stated for the materials of following components:*

Assembly/ Components	Food contact Material i.e.	Material name	Conformity reference
Sensor	Stainless steel Titanium Tantal  Aluminium oxyde	<ul style="list-style-type: none"><li>1.4435/316L</li><li>1.4404</li><li>1.4539</li><li>1.4571</li><li>3.7194</li><li>Alloy C4/C22/C276</li><li>Ti</li><li>Ta</li><li>Al2O3</li></ul>	1935/2004 1935/2004 Guideline for metal and alloys (Council of Europe 03/2001) CFR 21 Part 186.1256(FDA)
Sensor Coating	Teflon	<ul style="list-style-type: none"><li>PTFE</li><li>PFA</li><li>PVDF</li></ul>	CFR 21 Part 177.1550 177.2415 177.2510(FDA) 10/2011
Sensor Seals	Elastomers	<ul style="list-style-type: none"><li>EPDM</li><li>HNBR</li><li>FKM (Viton)</li><li>Silicone</li><li>Kalrez</li></ul>	CFR 21 Part 177.2600 177.2600 177.2600 177.2600 177.2600(FDA)
Sensor Plastic material	Plastic	<ul style="list-style-type: none"><li>PEEK™ (Victrex®)</li></ul>	EU Regulations 2002/72/EC (N/A) 10/2011/EU
Sensor Filling	Oil	<ul style="list-style-type: none"><li>Silicon oil</li><li>Edible oil</li><li>BERUSYNTH</li><li>Neobee M20</li></ul>	CFR 21 Part - 175.105 182.20 178.3570 172.856

Denne erklæring gælder udelukkende for sensoren, fremstillet af ovennævnte materiale, ikke for evt. medfølgende pakninger.

*This declaration of conformity is stated only for the sensor manufactured from the above listed materials, not for supplied seals*



Det bekræftes hermed, at kun de monomerer som er opført i bilag II til Kommissionens direktiv 2002/72 / EF med senere ændringer, til og med Kommissionens direktiv EF 2010/169 / EU og også Kommissionens Regel 10/2011 / EU anvendes under fremstillingen af Victrex® PEEK™

*It is confirmed that only those monomers listed in Annex II of Commission Directive 2002/72/EC and its subsequent amendments, up to and including Commission Directive EC 2010/169/EU and also the Commission Regulation 10/2011/EU are used in the manufacture of Victrex® PEEK™*

Monomererne 4,4'-difluorbenzophenon (PM / REF-nr 15820) og 1,4-dihydroxybenzen (PM / ref nr. 15940), der anvendes til fremstilling af Victrex® PEEK™ er underlagt specifikke migrationsgrænser på 0,05 mg / kg og 0,6 mg / kg i fødevarer eller fødevarer simulatorer.

*The monomers 4,4'-difluorobenzophenone (PM/REF No 15820) and 1,4-dihydroxybenzene (PM/ref No15940), used in the manufacture of Victrex® PEEK™ are subject to specific migration limits of 0.05 mg/kg and 0.6 mg/kg in food or food simulants, respectively.*

Additivet, diphenyl sulfon, (PM / Ref nr 51570), der anvendes til fremstilling af Victrex® PEEK™ er omfattet af en specifik migrationsgrænse på 3 mg / kg i fødevarer eller fødevarer simulatorer.

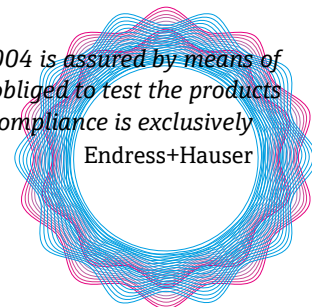
*The additive, diphenyl sulphone, (PM/Ref No 51570), used in the manufacture of Victrex® PEEK™ is subject to a specific migration limit of 3 mg/kg in food or food simulants.*

Overholdelse af den samlede migrationsgrænse samt specifikke migrationsgrænser i Kommissionens direktiv 2002/72 / EF, eller Kommissionens Regel 10/2011 / EU fremgår af prøvninger udført på det færdige produkt.

*Compliance with the overall migration limit and specific migration limits of Commission Directive 2002/72/EC (N/A), as amended or Commission Regulation 10/2011/EU is demonstrated by tests carried out on the final article.*

Sporbarhed i henhold til direktiv 1935/2004 sikres ved mærkning af hvert instrument med et unikt serienummer. Dette for at understrege at kunden er forpligtet til at teste instrumentet og dets egnethed i applikationen. Denne overensstemmelseserklæring er gyldig, udelukkende for de listede produkter, som fortsat kan leveres.

*Traceability of product in accordance with Regulation (EC) 1935/2004 is assured by means of serial number on sensor. This is to emphasize that the customer is obliged to test the products with regard to its suitability in the application. This declaration of compliance is exclusively valid for the listed products in delivery status.*



# Overensstemmelseserklæring Declaration of Conformity

Denne overensstemmelseserklæring er gyldig for de nævnte produkter, der er fremstillet inden for 2 år efter datoen for denne erklæring, med forbehold for tekniske ændringer.

*This declaration is only valid for the listed products, which are produced not later than 2 years after the issuing date of this declaration, under restriction of technical changes only.*

Ved ændringer i gældende regler/forordninger, opdateres nærværende erklæring i henhold til udstedte retningslinjer

*Changes in current rules / regulation will be updated in this declaration in accordance with the guidelines issued.*

Søborg den 16. august 2021/August 16th 2021  
Endress+Hauser A/S



---

Jens Fuglsang, Adm. Direktør

