



KONFORMITÄTSERKLÄRUNG DECLARATION OF CONFORMITY



In-vitro-Diagnostika
IVD
Reagenzien & Testkits

In Vitro Diagnostics
IVD
Reagents & Test kits

(1/X)
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Mit diesem Zertifikat erklären wir

Bioanalytic GmbH
Waldmatten 10-13
79224 Umkirch
SRN: DE-MF-000005562

in alleiniger Verantwortung:

Die nachstehend gelisteten In-vitro-Diagnostika (IVD) sind konform mit:

- Verordnung (EU) 2017/746 (IVDR) des Europäischen Parlaments und des Rates

Die Herstellung erfolgt unter Berücksichtigung der folgenden normativen und weiteren Dokumenten:

- EN ISO 13485
- Interne Herstellungsvorschrift (SOP)
- Interne Qualitätskontrolle (IQC)
- Freigabeprozedur

Diese Konformitätserklärung ersetzt für alle gelisteten In-vitro-Diagnostika ein chargenabhängiges Analysenzertifikat.

With this certificate we

Bioanalytic GmbH
Waldmatten 10-13
79224 Umkirch
SRN: DE-MF-000005562

declare on our own responsibility:

The below stated in vitro diagnostic products (IVDs) are in conformity with:

- Regulation (EU) 2017/746 (IVDR) of the European Parliament and of the Council

The production takes place with consideration to the following normative and other standard documents:

- EN ISO 13485
- Internal Manufacturing SOP
- Internal Quality Control (IQC)
- Release Procedure

This Declaration of Conformity replaces for all listed in vitro diagnostics a batch depending Certificate of Analysis.

Declaration of Conformity
IVD-Reagents & Test Kits

(de/en)

CON-IVDR-LIST

Gültigkeit:

Die vorstehende Konformitätserklärung ist gültig

- ausschließlich für unveränderte und original etikettierte Bioanalytic-Produkte.
- für alle Produkte, aufgeführt im Anhang unten bis "Ende der Liste".
- bis zum Ablaufdatum des CE gekennzeichneten Produkts (siehe Etikett).

Diese Konformitätserklärung verliert ihre Gültigkeit mit der Ausstellung einer neuen Konformitätserklärung spätestens jedoch zum 2024-12-12.

Validity:

The above Declaration of Conformity is valid

- exclusively for unmodified and original labeled Bioanalytic products.
- for the products listed in the appendix below until "End of List".
- up to the exp. date of the CE marked product (see label).

This declaration of conformity ceases to be valid with the issue of a new declaration of conformity but at latest by 2024-12-12.

Dr. Ferdinand M. Rüdinger
Managing Director

2022-05-23





Product List

REF	Name	Basis UDI DI	Class
004005-6010	Leuko-TIC VT (Viability Test Staining)	4061609-0001-NM	A
004005-6100	Leuko-TIC VT plus (Viability Test Staining)	4061609-0001-NM	A
004008-6010	Leuko-TIC SF 1:100 (Synovial Fluid)	4061609-0002-NQ	A
004008-6100	Leuko-TIC SF 1:100 plus (Synovial Fluid)	4061609-0002-NQ	A
004012-0006	Ery-TIC 1 : 200 'pur' (100 pcs) [PAC]	4061609-0003-NT	A
004012-0007	Ery-TIC 1 : 200 'pur' plus (100 pcs incl. capillaries) [KIT]	4061609-0003-NT	A
004012-0100	EryCount 'pur' (100 ml)	4061609-0003-NT	A
004012-0500	EryCount 'pur' (500 ml)	4061609-0003-NT	A
004012-6010	Ery-TIC 1 : 200 'pur' (10 pcs Sachet)	4061609-0003-NT	A
004013-0006	Leuko-TIC 1 : 20 'blue' (100 pcs) [PAC]	4061609-0004-NW	A
004013-0007	Leuko-TIC 1 : 20 'blue' plus (100 pcs incl. capillaries) [KIT]	4061609-0004-NW	A
004013-0100	LeukoCount 'blue' (100ml)	4061609-0004-NW	A
004013-0500	LeukoCount 'blue' (500ml)	4061609-0004-NW	A
004013-6010	Leuko-TIC 1 : 20 'blue' (10 pcs Sachet) [PAC]	4061609-0004-NW	A
004014-0100	LeukoCount 'pur' (100 ml)	4061609-0004-NW	A
004015-0006	Thrombo-TIC 1 : 100 'pur' (100 pcs) [PAC]	4061609-0005-NZ	A
004015-0007	Thrombo-TIC 1 : 100 'pur' plus (100 pcs incl. capillaries) [KIT]	4061609-0005-NZ	A
004015-0050	ThromboCount 'pur' (50 ml)	4061609-0005-NZ	A
004015-0100	ThromboCount 'pur' (100 ml)	4061609-0005-NZ	A
004015-6010	Thrombo-TIC 1 : 100 'pur' (10 pcs Sachet) [PAC]	4061609-0005-NZ	A
004015-6011DMD	Thrombo-TIC 1 : 100 'pur'	4061609-0005-NZ	A
004015-6012DMD	Thrombo-TIC 1 : 25 (480 µl)	4061609-0005-NZ	A
004015-6013DMD	Thrombo-TIC 1 : 25 (480 µl)	4061609-0005-NZ	A
ETE005-0100	ETE Capillaries 5 µl • Accuracy ±0.50%, CV 0.75 % Manufactured acc. ISO 7550	4061609-0006-P4	A
ETE010-0100	ETE Capillaries 10 µl • Accuracy ±0.50%, CV 0.75 % Manufactured acc. ISO 7550	4061609-0006-P4	A
ETE020-0100	ETE Capillaries 20 µl • Accuracy ±0.50%, CV 0.60 % Manufactured acc. ISO 7550	4061609-0006-P4	A
KFK-0100	Kammerfüllkapillaren	4061609-0006-P4	A
TIC-CP05	TIC Capillary Pack 5 µl	4061609-0006-P4	A
TIC-CP10	TIC Capillary Pack 10 µl	4061609-0006-P4	A
TIC-CP20	TIC Capillary Pack 20 µl	4061609-0006-P4	A

Ende der Liste • Nicht aufgeführte Produkte auf Anfrage.

End of list • Not listed products on request.

Availability:
All products are available in EU. Availability for other countries on request.





KONFORMITÄTSERKLÄRUNG DECLARATION OF CONFORMITY



In-vitro-Diagnostika
IVD
Reagenzien, Standards & Testkits

In Vitro Diagnostics
IVD
Reagents, Standards & Test kits

(1/X)
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Mit diesem Zertifikat erklären wir in alleiniger Verantwortung:
Die nachstehend gelisteten In-vitro-Diagnostika (IVD) sind konform mit:

- Richtlinie 98/79/EG
Richtlinie des Rates über „In-vitro-Diagnostika“
- Konformitätsbewertungsverfahren:
98/79/EG Anhang III.

Die Herstellung erfolgt unter Berücksichtigung der folgenden normativen und weiteren Dokumenten:

- EN ISO 13485
- Interne Herstellungsvorschrift (SOP)
- Interne Qualitätskontrolle (IQC)
- Freigabeprozedur

Diese Konformitätserklärung ersetzt für alle gelisteten In-vitro-Diagnostika ein chargenabhängiges Analysenzertifikat.

With this certificate we declare on our own responsibility:
The below stated in vitro diagnostic products (IVDs) are in conformity with:

- Directive 98/79/EG
Directive of the council about „in vitro diagnostics“
- Conformity assessment procedure:
98/79/EG Appendix III.

The production takes place with consideration to the following normative and other standard documents:

- EN ISO 13485
- Internal Manufacturing SOP
- Internal Quality Control (IQC)
- Release Procedure

This Declaration of Conformity replaces for all listed in vitro diagnostics a batch depending Certificate of Analysis.

Declaration of Conformity
IVD-Reagents, Standards & Test Kits

(de/en)

CON-IVDD-LIST

Gültigkeit:

- Die vorstehende Konformitätserklärung ist gültig
- ausschließlich für unveränderte und original etikettierte Bioanalytic-Produkte.
 - für alle Produkte, aufgeführt im Anhang unten bis "Ende der Liste".
 - bis zum Ablaufdatum des CE gekennzeichneten Produkts (siehe Etikett).

Validity:

- The above Declaration of Conformity is valid
- exclusively for unmodified and original labeled Bioanalytic products.
 - for the products listed in the appendix below until "End of List".
 - up to the exp. date of the CE marked product (see label).

Dr. Ferdinand M. Rüdinger
Managing Director

2020-08-06





Product List

002527-7100	Natriumhypochlorit 0.95% (akt. Cl)	004015-6012DMD	Thrombo-TIC 1 : 25 (480 µl)
002527-7500	Natriumhypochlorit 0.95% (akt. Cl)	004015-6013DMD	Thrombo-TIC 1 : 25 (480 µl)
002527-1010.01	Natriumhypochlorit 0.5% (akt. Cl)	004016-0100	Brillant kresyl blue stain solution isotonic (100 ml)
003501-...	SediDiff	004016-0006	Reti-TIC (100 pcs) [PAC]
003503-...	Sternheimer-Malbin Concentrate	004016-6010	Reti-TIC (10 pcs Sachet) [PAC]
003604-6005	Sperm-TIC (5 pcs • Sachet)	004017-0100	Brillant kresyl blue stain solution alcoholic (100 ml)
003604-6100	Sperm-TIC (100 pcs • incl. capillaries) [KIT]	004018-0050	ThromboCount 'fix' (50 ml)
003820-...	Gram Stain	004018-0100	ThromboCount 'fix' (100 ml)
003821-...	Crystal Violet	004019-0100	Eos-TIC 1:32 plus (100 ml)
003822-...	Carbol Gentiana Violet	004019-6010	Eos-TIC 1:32 plus (10 pcs Sachet) [PAC]
003421-...	Lugol's Solution	004019-6100	Eos-TIC 1:32 plus (100 pcs incl. capillaries) [KIT]
003823-...	Gram's Destaining Solution	004100-...	HemaDiff Set
003824-...	Safranin Solution	004101-...	HemaDiff A (Fix Solution)
003825-...	Ziehl-Neelson Solution	004102-...	HemaDiff B (red)
003830-...	Tb Stain	004103-...	HemaDiff C (blue)
003831-...	Tb-Stain Sputusolve	004111-...	HemaDiff Buffer Concentrate • pH = 6.4
003832-...	Tb-Stain Carbol Fuchsin	004112-...	HemaDiff Buffer Solution • pH = 6.4
003833-...	Tb-Stain Destaining Solution	004121-...	HemaDiff Buffer Concentrate • pH = 6.8
003834-...	Tb-Stain Malachite green	004122-...	HemaDiff Buffer Solution • pH = 6.8
003851-...	Eosin-Nigrosin (buffered, ready for use)	004131-...	HemaDiff Buffer Concentrate • pH = 7.2
003860-6001	Eosin & Nigrosin (separate solutions)	004132-...	HemaDiff Buffer Solution • pH = 7.2
004001-1010	Hemoglobin Reagent (Hb) = improved and standardized Drabkin's solution	004521-...	IsoDil (Isotonic Diluent) (A)
004001-1025	Hemoglobin Reagent (Hb) = improved and standardized Drabkin's solution	004623-...	Cyanhämglobin Standard for Hemoglobin ICSH/CLSI 10.0 g/dlHb (1:251)
004001-0250	free Hemoglobin Reagent (fHb HiCN method)	004624-...	Cyanhämglobin Standard for Hemoglobin ICSH/CLSI 15.0 g/dlHb (1:251)
004002-...	Erythrozyten • Gower's Reagent	004631-...	Cyanhämglobin Standard for free Hemoglobin 12.0 mg/dl fHb
004003-...	free Hemoglobin (fHb 3-wavelength method Harboe)	004710-...	CounterClean E [KIT]
004012-0100	EryCount 'pur' (100 ml)	004711-...	CounterClean Buffer
004012-0500	EryCount 'pur' (500 ml)	004712-...	CounterClean Enzyme
004012-0006	Ery-TIC 1 : 200 'pur' (100 pcs) [PAC]	004460-...	EryLysin (A)
004012-6010	Ery-TIC 1 : 200 'pur' (10 pcs Sachet)	004461-...	EryLysin Hb (A)
004012-0007	Ery-TIC 1 : 200 'pur' plus (100 pcs incl. capillaries) [KIT]	005101-...	Aqua IVD
004013-0100	LeukoCount 'blue' (100ml)	005223-...	NaOH 20%
004013-0500	LeukoCount 'blue' (500ml)	006501-...	Eisen Feren [KIT]
004013-0006	Leuko-TIC 1 : 20 'blue' (100 pcs) [PAC]	006502-...	Eisen Ferrozin [KIT]
004013-0007	Leuko-TIC 1 : 20 'blue' plus (100 pcs incl. capillaries) [KIT]	006513-...	Eisen Ferrozin [KIT]
004013-6010	Leuko-TIC 1 : 20 'blue' (10 pcs Sachet) [PAC]	006514-...	Eisen Feren [KIT]
004014-0100	LeukoCount 'pur' (100 ml)	006516-...	Eisen Standard 25.0 µmol/l
004015-0050	ThromboCount 'pur' (50 ml)	006570-...	Eisen Ferrozin TGA [KIT]
004015-0100	ThromboCount 'pur' (100 ml)	006603-...	Protein Standard 6.0 g/dl = 60 g/l
004015-0006	Thrombo-TIC 1 : 100 'pur' (100 pcs) [PAC]	006610-...	Protein Concentrate [KIT]
004015-0007	Thrombo-TIC 1 : 100 'pur' plus (100 pcs incl. capillaries) [KIT]	006611-...	Protein Biuret Reagent Concentrate
004015-6011DMD	Thrombo-TIC 1 : 100 'pur'		





006612-...	Protein Blank Reagent Concentrate		050037-...	McFarland 6.0 MFU (PMS = Polymer Microparticle Suspension)
006621-...	Protein Biuret Reagent		050038-...	McFarland 7.0 MFU (PMS = Polymer Microparticle Suspension)
006622-...	Protein Blank Reagent		050039-...	McFarland 8.0 MFU (PMS = Polymer Microparticle Suspension)
006641-...	Protein AU5000 Blank Reagent	(A)	085110-7100	Pluronic® F-68 Solution (10% w/v) (100 ml)
006642-...	Protein AU5000 Biuret Reagent	(A)	085110-7500	Pluronic® F-68 Solution (10% w/v) (500 ml)
006652-...	Protein MT Multi Test Kit	(A)	085202-0100	Ultra Pure Water
006688-...	Samson's Concentrate		200102-...	CAL • Na 160 • K 80.0 mmol/l (Urine)
006697-...	Nonne Apell's Reagent		200104-...	CAL • Na 120 • K 2.00 mmol/l (Urine)
006698-...	Pandy's Reagent		200118-...	CAL • Na 200 • K 100 mmol/l (Urine)
006802-...	Creatinin Standard 2.0 mg/dl = 20 mg/l		200119-...	CAL • Na 100 • K 100 mmol/l (Urine)
006803-...	Creatinin Standard 5.0 mg/dl = 50 mg/l		200120-...	CAL • Na 140 • K 5.00 • Ca 2.50 mmol/l (Serum)
009001-...	Citrate Sodium Chloride Buffer		200121-...	CAL • Na 140 • K 5.00 mmol/l (Serum)
009099-...	Sodium Citrate Solution 3.13%		200122-...	CAL • Na 140 • K 5.00 • Li 1.00 mmol/l (Serum-Li)
009100-...	Sodium Citrate Solution 3.8%		200150-...	CAL • Na 140 • K 5.00 • Li 1.50 mmol/l (Serum-Li)
009101-0100.10	Sodium Citrate Solution 0.11 mol/l		200201-...	Internal Lithium Standard • Li 3000 mmol/l
009101-0100.20	Sodium Citrate Solution 3.13%		200211-...	Internal Lithium Standard • Li 1500 mmol/l
009101-0100.30	Sodium Citrate Solution 3.8%		200251-...	Internal Cäsium Standard • Cs 1.5 mmol/L
009102-...	Sodium Citrate Solution 0.1 mol/l, pH = 4.65		200800-...	Acid Buffer Solution
009141-...	TRIS Buffer Salt Solution pH = 7.50		200810-...	Gelatin Indicator Solution
009142-...	Imidazole-Buffer		200821-...	Chloride Standard (clinical) Cl 100 mmol/l
009151-...	Calcium Chloride 25 mmol/l = 0.025 mol/l		300002-...	System-Leerwert-Konzentrat
009152-...	Calcium Chloride 10 mmol/l = 0.010 mol/l		300104-...	CAL • Na 143.5 • K 3.84 • Ca 2.50 • Li 2.0 mmol/l (Serum)
009153-...	Calcium Chloride 50 mmol/l = 0.050 mol/l		300106-...	CAL • Na 143.5 • K 100.0 • Ca 5.00 • (P 0.97) mmol/l (Urine)
009154-...	Calcium Chloride 3.2 mmol/l		300150-...	Lithium-Stammlösung • Li 500.0 mmol/l
009155-...	Calcium Chloride 20 mmol/l = 0.020 mol/l		520001-...	CAL 1 • pH = 7.383 (37°C) • SOL #3
010411-...	NTX-Electrophoresis Buffer pH = 8.6		520002-...	CAL 2 • pH = 6.841 (37°C) • SOL #4
040100-...	Osmolality Calibration Zero • 0 mosm/kg H ₂ O		520003-...	Rinse Solution • SOL # 5 Rinse Solution • Enzym
040103-...	Osmolality Calibration Standard • 300 mosm/kg H ₂ O		520004-...	Deproteinizer (alkaline)
040104-...	Osmolality Calibration Standard • 400 mosm/kg H ₂ O		520005-...	Cleaning Solution (alkaline)
040105-...	Osmolality Calibration Standard • 500 mosm/kg H ₂ O		520011-...	SOL # 1 Cleaning Solution
050001-...	McFarland BSS Stock Concentrate A		520012-...	SOL # 2 Salt Bridge Solution
050002-...	McFarland BSS Stock Concentrate A		520013-...	Rinse Solution
050011-...	McFarland 0.5 MFU (BSS = Barium Sulphate Suspension)		ETE005-0100	ETE Capillaries 5 µl • Accuracy ±0.50%, CV 0.75 % Manufactured acc. ISO 7550 & EN ISO 13485
050012-...	McFarland 1.0 MFU (BSS = Barium Sulphate Suspension)		ETE010-0100	ETE Capillaries 10 µl • Accuracy ±0.50%, CV 0.75 % Manufactured acc. ISO 7550 & EN ISO 13485
050013-...	McFarland 2.0 MFU (BSS = Barium Sulphate Suspension)		ETE020-0100	ETE Capillaries 20 µl • Accuracy ±0.50%, CV 0.60 % Manufactured acc. ISO 7550 & EN ISO 13485
050014-...	McFarland 3.0 MFU (BSS = Barium Sulphate Suspension)		TIC-CP05	TIC Capillary Pack 5 µl
050015-...	McFarland 4.0 MFU (BSS = Barium Sulphate Suspension)		TIC-CP20	TIC Capillary Pack 10 µl
050016-...	McFarland 5.0 MFU (BSS = Barium Sulphate Suspension)		TIC-CP20	TIC Capillary Pack 20 µl
050017-...	McFarland 6.0 MFU (BSS = Barium Sulphate Suspension)		S00101	Kristallviolett-Lösung 1.3 % in Wasser (S)
050018-...	McFarland 7.0 MFU (BSS = Barium Sulphate Suspension)		Ende der Liste • Nicht aufgeführte Produkte auf Anfrage.	
050019-...	McFarland 8.0 MFU (BSS = Barium Sulphate Suspension)		End of list • Not listed products on request.	
050031-...	McFarland 0.5 MFU (PMS = Polymer Microparticle Suspension)			
050032-...	McFarland 1.0 MFU (PMS = Polymer Microparticle Suspension)			
050033-...	McFarland 2.0 MFU (PMS = Polymer Microparticle Suspension)			
050034-...	McFarland 3.0 MFU (PMS = Polymer Microparticle Suspension)			
050035-...	McFarland 4.0 MFU (PMS = Polymer Microparticle Suspension)			
050036-...	McFarland 5.0 MFU (PMS = Polymer Microparticle Suspension)			

Availability:
All products are available in EU. Availability for other countries on request.

