



KONFORMITÄTSERKLÄRUNG DECLARATION OF CONFORMITY



In-vitro-Diagnostika IVD Reagenzien, Standards & Testkits

In Vitro Diagnostics IVD Reagents, Standards & Test kits

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.

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).

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Manager of Manufacturing

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Product List

002527-7100	Natriumhypochlorit 0.95% (akt. Cl) (100 ml)	004016-0006	Reti-TIC (100 pcs • Box)
002527-7500	Natriumhypochlorit 0.95% (akt. Cl) (500 ml)	004016-6010	Reti-TIC (10 pcs • Sachet)
003501-...	SediDiff	004017-0100	Brillant kresyl blue stain solution alcoholic (100 ml)
003503-...	Sternheimer-Malbin Concentrate	004018-0050	ThromboCount 'fix' (50 ml)
003604-6005	Sperm-TIC (5 pcs • Sachet)	004018-0100	ThromboCount 'fix' (100 ml)
003604-6100	Sperm-TIC (100 pcs • Kit incl. capillaries)	004019-0100	Eos-TIC 1:32 plus (100 ml)
003820-...	Gram's Stain Set	004019-6010	Eos-TIC 1:32 plus (10 pcs • Sachet)
003821-...	Crystal Violet	004019-6100	Eos-TIC 1:32 plus (100 pcs • Kit incl. capillaries)
003822-...	Carbol Gentiana Violet	004100-...	HemaDiff Set
003421-...	Lugol's Solution	004101-...	HemaDiff A (Fix Solution)
003823-...	Gram's Destaining Solution	004102-...	HemaDiff B (red)
003824-...	Safranin Solution	004103-...	HemaDiff C (blue)
003825-...	Ziehl-Neelson Solution	004111-...	HemaDiff Buffer Concentrate • pH = 6.4
003830-...	Tb Stain Set	004112-...	HemaDiff Buffer Solution • pH = 6.4
003831-...	Tb-Stain Sputosolve	004121-...	HemaDiff Buffer Concentrate • pH = 6.8
003832-...	Tb-Stain Carbol Fuchsin	004122-...	HemaDiff Buffer Solution • pH = 6.8
003833-...	Tb-Stain Destaining Solution	004131-...	HemaDiff Buffer Concentrate • pH = 7.2
003834-...	Tb-Stain Malachite green	004132-...	HemaDiff Buffer Solution • pH = 7.2
003851-...	Eosin-Nigrosin (buffered, ready for use)	004521-...	IsoDil (Isotonic Diluent) (A)
003860-6001	Eosin & Nigrosin (Kit of separate solutions)	004623-...	Cyanhämoglobin Standard for Hemoglobin ICSH/CLSI 10.0 g/dlHb (1:251)
004001-1010	Hemoglobin Reagent (Hb) • = improved and standardized Drabkin's solution	004624-...	Cyanhämoglobin Standard for Hemoglobin ICSH/CLSI 15.0 g/dlHb (1:251)
004001-1025	Hemoglobin Reagent (Hb) • = improved and standardized Drabkin's solution	004631-...	Cyanhämoglobin Standard for free Hemoglobin 12.0 mg/dl fHb
004001-0250	free Hemoglobin Reagent (fHb HiCN method)	004710-...	CounterClean E Kit
004002-...	Erythrozyten • Gower's Reagent	004711-...	CounterClean Buffer
004003-...	free Hemoglobin (fHb 3-wavelength method Harboe)	004712-...	CounterClean Enzyme
004012-0100	EryCount 'pur' (100 ml)	004460-...	EryLysin (A)
004012-0500	EryCount 'pur' (500 ml)	004461-...	EryLysin Hb (A)
004012-0006	Ery-TIC 1 : 200 'pur' (100 pcs • Box)	005223-...	NaOH 20%
004012-6010	Ery-TIC 1 : 200 'pur' (10 pcs • Sachet)	006501-...	Eisen Feren (Test Kit)
004012-0007	Ery-TIC 1 : 200 'pur' plus (100 pcs • Kit incl. capillaries)	006502-...	Eisen Ferrozin (Test Kit)
004013-0100	LeukoCount 'blue' (100ml)	006513-...	Eisen Ferrozin
004013-0500	LeukoCount 'blue' (500ml)	006514-...	Eisen Feren
004013-0006	Leuko-TIC 1 : 20 'blue' (100 pcs • Box)	006516-...	Eisen Standard 25.0 µmol/l
004013-0007	Leuko-TIC 1 : 20 'blue' plus (100 pcs • Kit incl. capillaries)	006603-...	Protein Standard 6.0 g/dl = 60 g/l
004013-6010	Leuko-TIC 1 : 20 'blue' (10 pcs • Sachet)	006610-...	Protein (Concentrate Test Kit)
004014-0100	LeukoCount 'pur' (100 ml)	006611-...	Protein Biuret Reagent Concentrate
004015-0050	ThromboCount 'pur' (50 ml)	006612-...	Protein Blank Reagent Concentrate
004015-0100	ThromboCount 'pur' (100 ml)	006621-...	Protein Biuret Reagent
004015-0006	Thrombo-TIC 1 : 100 'pur' (100 pcs • Box)	006622-...	Protein Blank Reagent
004015-0007	Thrombo-TIC 1 : 100 'pur' plus (100 pcs • Kit incl. capillaries)	006641-...	Protein AU5000 Blank Reagent (A)
004015-6012DMD	Thrombo-TIC 1 : 25 (480 µl)	006642-...	Protein AU5000 Biuret Reagent (A)
004016-0100	Brillant kresyl blue stain solution isotonic (100 ml)		





006652-...	Protein MT Multi Test Kit	(A)
006688-...	Samson's Concentrate	
006697-...	Nonne Apelt's Reagent	
006698-...	Pandy's Reagent	
006802-...	Creatinin Standard 2.0 mg/dl = 20 mg/l	
006803-...	Creatinin Standard 5.0 mg/dl = 50 mg/l	
009001-...	Citrate Sodium Chloride Buffer	
009099-...	Sodium Citrate Solution 3.13%	
009100-...	Sodium Citrate Solution 3.8%	
009101-0100.10	Sodium Citrate Solution 0.11 mol/l	
009101-0100.20	Sodium Citrate Solution 3.13%	
009101-0100.30	Sodium Citrate Solution 3.8%	
009102-...	Sodium Citrate Solution 0.1 mol/l, pH = 4.65	
009141-...	TRIS Buffer Salt Solution pH = 7.50	
009142-...	Imidazole-Buffer	
009151-...	Calcium Chloride 25 mmol/l = 0.025 mol/l	
009152-...	Calcium Chloride 10 mmol/l = 0.010 mol/l	
009153-...	Calcium Chloride 50 mmol/l = 0.050 mol/l	
009154-...	Calcium Chloride 3.2 mmol/l	
009155-...	Calcium Chloride 20 mmol/l = 0.020 mol/l	
010411-...	NTX-Electrophoresis Buffer pH = 8.6	
040100-...	Osmolality Calibration Zero • 0 mosm/kg H ₂ O	
040103-...	Osmolality Calibration Standard • 300 mosm/kg H ₂ O	
040104-...	Osmolality Calibration Standard • 400 mosm/kg H ₂ O	
040105-...	Osmolality Calibration Standard • 500 mosm/kg H ₂ O	
050011-...	McFarland 0.5 MFU (BSS = Barium Sulphate Suspension)	
050012-...	McFarland 1.0 MFU (BSS = Barium Sulphate Suspension)	
050013-...	McFarland 2.0 MFU (BSS = Barium Sulphate Suspension)	
050014-...	McFarland 3.0 MFU (BSS = Barium Sulphate Suspension)	
050015-...	McFarland 4.0 MFU (BSS = Barium Sulphate Suspension)	
050016-...	McFarland 5.0 MFU (BSS = Barium Sulphate Suspension)	
050017-...	McFarland 6.0 MFU (BSS = Barium Sulphate Suspension)	
050018-...	McFarland 7.0 MFU (BSS = Barium Sulphate Suspension)	
050019-...	McFarland 8.0 MFU (BSS = Barium Sulphate Suspension)	
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)	
050037-...	McFarland 6.0 MFU (PMS = Polymer Microparticle Suspension)	
050038-...	McFarland 7.0 MFU (PMS = Polymer Microparticle Suspension)	
050039-...	McFarland 8.0 MFU (PMS = Polymer Microparticle Suspension)	
085110-7100	Pluronic® F-68 Solution (10% w/v) (100 ml)	
085110-7500	Pluronic® F-68 Solution (10% w/v) (500 ml)	
085202-0100	Ultra Pure Water	

S00101 Kristallviolett-Lösung 1.3 % in Wasser (S)

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.

