

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).

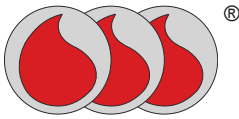
Validity:

- 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).

Dr. Ferdinand M. Rüdinger
Managing Director

2019-07-06

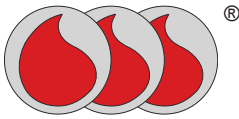




Product List

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|----------------|---|----------------|--|
| 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' | | |





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| 006612-... | Protein Blank Reagent Concentrate | |
| 006621-... | Protein Biuret Reagent | |
| 006622-... | Protein Blank Reagent | |
| 006641-... | Protein AU5000 Blank Reagent | (A) |
| 006642-... | Protein AU5000 Biuret Reagent | (A) |
| 006652-... | Protein MT Multi Test Kit | (A) |
| 006688-... | Samson's Concentrate | |
| 006697-... | Nonne Apell'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 | |
| 050001-... | McFarland BSS Stock Concentrate A | |
| 050002-... | McFarland BSS Stock Concentrate A | |
| 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) | |

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|-------------|---|-----|
| 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 | |
| 200102-... | CAL • Na 160 • K 80.0 mmol/l (Urine) | |
| 200104-... | CAL • Na 120 • K 2.00 mmol/l (Urine) | |
| 200119-... | CAL • Na 100 • K 100 mmol/l (Urine) | |
| 200120-... | CAL • Na 140 • K 5.00 • Ca 2.50 mmol/l (Serum) | |
| 200121-... | CAL • Na 140 • K 5.00 mmol/l (Serum) | |
| 200122-... | CAL • Na 140 • K 5.00 • Li 1.00 mmol/l (Serum-Li) | |
| 200150-... | CAL • Na 140 • K 5.00 • Li 1.50 mmol/l (Serum-Li) | |
| 200201-... | Internal Lithium Standard • Li 3000 mmol/l | |
| 200211-... | Internal Lithium Standard • Li 1500 mmol/l | |
| 200251-... | Internal Cäsium Standard • Cs 1.5 mmol/L | |
| ETE005-0100 | ETE Capillaries 5 µl • Accuracy ±0.50%, CV 0.75 % Manufactured acc. ISO 7550 & EN ISO 13485 | |
| ETE010-0100 | ETE Capillaries 10 µl • Accuracy ±0.50%, CV 0.75 % Manufactured acc. ISO 7550 & EN ISO 13485 | |
| ETE020-0100 | ETE Capillaries 20 µl • Accuracy ±0.50%, CV 0.60 % Manufactured acc. ISO 7550 & EN ISO 13485 | |
| TIC-CP05 | TIC Capillary Pack 5 µl | |
| TIC-CP20 | TIC Capillary Pack 10 µl | |
| TIC-CP20 | TIC Capillary Pack 20 µl | |
| 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.

