

Certificate

mdc medical device certification GmbH
certifies that

Human

Gesellschaft für Biochemica und Diagnostica mbH
Max-Planck-Ring 21
65205 Wiesbaden
Germany

with the location

Stegelitzer Straße 3
39126 Magdeburg

for the scope

development, manufacturing and distribution of
in vitro diagnostic products and analyzers

has introduced and applies a

Quality Management System

The mdc audit has proven that this quality management system
meets all requirements of the following standard

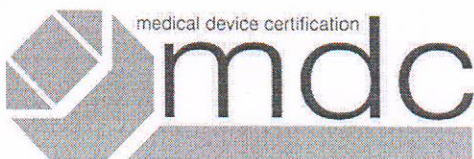
EN ISO 13485

Medical devices – Quality management systems –
Requirements for regulatory purposes

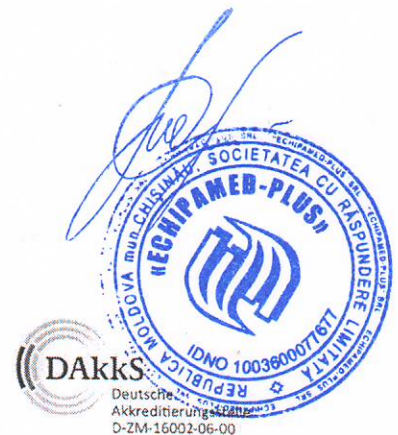
EN ISO 13485:2016 + AC:2016 - ISO 13485:2016

| | |
|------------------|------------------|
| Valid from | 2019-03-12 |
| Valid until | 2022-03-11 |
| Registration no. | D1030000073 |
| Report no. | P18-01225-128829 |
| Stuttgart | 2019-03-01 |


Head of Certification Body



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Internet: <http://www.mdc-ce.de>



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Quality management system

The mdc audit has proven that this quality management system
meets all requirements of the following standard

EN ISO 9001

Quality management systems –
Requirements
(ISO 9001:2015)

| | |
|------------------|------------------|
| Valid from | 2018-03-16 |
| Valid until | 2021-03-15 |
| Registration no. | D1030000066 |
| Report no. | P17-01410-107299 |
| Stuttgart | 2018-03-16 |


Head of Certification Body



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Declaration of Conformity



We,

HUMAN Gesellschaft für Biochemica und Diagnostica mbH
Max-Planck-Ring 21
65205 Wiesbaden
Germany

hereby confirm that we have installed a quality management system according to the harmonized standards EN ISO 9001:2015 and EN ISO 13485:2016+AC:2016. Our quality management system has been certified for compliance with said standards by the German Notified Body mdc medical device certification GmbH, Kriegerstr. 6, D-70191 Stuttgart, registered under reference number 0483, respectively (certificates registration numbers are D1030000072 and D1030000073).

Compliance with additional requirements of annex IV (directive 98/79 EC) for products classified as either annex II list A or list B has been certified by the German Notified Body mdc (reg. nos.: D1030000076, D1030000075, D1030000048, D1030000049, D1030000062, D1030000063 and D1030000068 respectively).

We further confirm that the IVD products listed in the attachment are designed, manufactured and controlled by us in accordance with the European directive 98/79 EC and that they meet the essential requirements according to annex I of said directive. Applicable conformity assessment procedures according to annex III (denoted others or H in the attached list) or annex IV (denoted II, A or II, B), whatever applicable, of said directive have been completed for these products. We further confirm that for each IVD product an individual conformity declaration has been prepared.

With the **CE** mark on the listed products we declare in our sole responsibility that the products are in conformity with the applicable directive 98/79/EC and harmonized standards.

HUMAN Gesellschaft für Biochemica und Diagnostica mbH

Date: November 01, 2019

Dr. Torsten Borchers
Vice President Quality Assurance and Regulatory Affairs

Human

Gesellschaft für Biochemica
und Diagnostica mbH
Max-Planck-Ring 21
65205 Wiesbaden-Deilkenheim
Germany

Attachment



List of products which passed applicable conformity assessment procedures
(annex III, annex IV of directive 98/79/EC) by date of signing

| Cat.-no. | Product name | Class |
|----------|-------------------------------|--------|
| 10010 | Magnesium liquicolor | Others |
| 10010150 | Magnesium liquicolor | Others |
| 10010300 | Magnesium liquicolor | Others |
| 10010600 | Magnesium liquicolor | Others |
| 10011 | Calcium liquicolor | Others |
| 10011150 | Calcium liquicolor | Others |
| 10011300 | Calcium liquicolor | Others |
| 10011600 | Calcium liquicolor | Others |
| 10012 | Bilirubin liquicolor | Others |
| 10017 | Cholesterol liquicolor | Others |
| 10018 | HDL Cholesterol | Others |
| 10019 | Cholesterol liquicolor | Others |
| 10027 | Phosphorus liquirapid | Others |
| 10027150 | Phosphorus liquirapid | Others |
| 10027300 | Phosphorus liquirapid | Others |
| 10027600 | Phosphorus liquirapid | Others |
| 10028 | Cholesterol liquicolor | Others |
| 10028150 | Cholesterol liquicolor | Others |
| 10028300 | Cholesterol liquicolor | Others |
| 10028600 | Cholesterol liquicolor | Others |
| 10051 | Creatinine liquicolor | Others |
| 10052 | auto-Creatinine liquicolor | Others |
| 10052150 | auto-Creatinine liquicolor | Others |
| 10052300 | auto-Creatinine liquicolor | Others |
| 10052600 | auto-Creatinine liquicolor | Others |
| 10053 | Creatinine (Enzym) liquicolor | Others |
| 10053150 | Creatinine (Enzym) liquicolor | Others |
| 10053300 | Creatinine (Enzym) liquicolor | Others |
| 10053600 | Creatinine (Enzym) liquicolor | Others |
| 10084 | HDL Cholesterol liquicolor | Others |
| 10084150 | HDL Cholesterol liquicolor | Others |
| 10084300 | HDL Cholesterol liquicolor | Others |
| 10084600 | HDL Cholesterol liquicolor | Others |
| 10094 | LDL Cholesterol liquicolor | Others |
| 10094150 | LDL Cholesterol liquicolor | Others |
| 10094600 | LDL Cholesterol liquicolor | Others |
| 10104 | Urea Standard | Others |
| 10113 | Sodium liquicolor | Others |
| 10113150 | Sodium liquicolor | Others |
| 10113300 | Sodium liquicolor | Others |
| 10113600 | Sodium liquicolor | Others |
| 10114 | Sodium Standard | Others |
| 10115 | Chloride liquicolor | Others |
| 10118 | Potassium liquirapid | Others |

| Cat.-no. | Product name | Class |
|---------------------------|--|--------|
| 10120 | Potassium liquiUV | Others |
| 10120150 | Potassium liquiUV | Others |
| 10120300 | Potassium liquiUV | Others |
| 10120600 | Potassium liquiUV | Others |
| 10121 | Glucose liquicolor | Others |
| 10126 | Potassium Standard | Others |
| 10229 | Iron liquicolor | Others |
| 10230 | Iron liquicolor | Others |
| 10260 | Glucose liquicolor | Others |
| 10260150 | Glucose liquicolor | Others |
| 10260300 | Glucose liquicolor | Others |
| 10260600 | Glucose liquicolor | Others |
| 10284 | HDL Cholesterol liquicolor | Others |
| 10294 | LDL Cholesterol liquicolor | Others |
| 10505 | Urea liquicolor | Others |
| 10506 | Urea liquicolor R1 | Others |
| 10507 | Urea liquicolor R2 | Others |
| 10521 | Urea liquiUV | Others |
| 10521150 | Urea liquiUV | Others |
| 10521300 | Urea liquiUV | Others |
| 10521600 | Urea liquiUV | Others |
| 10560 | Albumin liquicolor | Others |
| 10560150 | Albumin liquicolor | Others |
| 10560300 | Albumin liquicolor | Others |
| 10560600 | Albumin liquicolor | Others |
| 10570 | Total Protein liquicolor | Others |
| 10570150 | Total Protein liquicolor | Others |
| 10570300 | Total Protein liquicolor | Others |
| 10570600 | Total Protein liquicolor | Others |
| 10590 | Urinary Total Protein liquicolor | Others |
| 10590300 | Urinary Total Protein liquicolor | Others |
| 10595 | Urinary Total Protein Standard | Others |
| 10657, 10658, 10259 | Glycohemoglobin HbA _{1c} | Others |
| 10660 | Acid Phosphatase Humazym | Others |
| 10660150 | Acid Phosphatase | Others |
| 10660600 | Acid Phosphatase | Others |
| 10670 | TIBC | Others |
| 10690 | Uric acid liquicolor | Others |
| 10691 | Uric acid liquicolor | Others |
| 10694 | Uric acid liquicolor ^{plus} | Others |
| 10694150 | Uric acid liquicolor ^{plus} | Others |
| 10694300 | Uric acid liquicolor ^{plus} | Others |
| 10694600 | Uric acid liquicolor ^{plus} | Others |
| 10720P | Triglycerides liquicolor ^{mono} | Others |



| Cat.-no. | Product name | Class |
|----------|--|--------|
| 10724 | Triglycerides liquicolor ^{mono} | Others |
| 10724150 | Triglycerides liquicolor ^{mono} | Others |
| 10724300 | Triglycerides liquicolor ^{mono} | Others |
| 10724600 | Triglycerides liquicolor ^{mono} | Others |
| 10725 | Triglycerides liquicolor ^{mono} | Others |
| 10740 | Bilirubin D&T liquicolor | Others |
| 10741 | auto-Bilirubin-D liquicolor | Others |
| 10741150 | auto-Bilirubin-D liquicolor | Others |
| 10741300 | auto-Bilirubin-D liquicolor | Others |
| 10741600 | auto-Bilirubin-D liquicolor | Others |
| 10742 | auto-Bilirubin-T liquicolor | Others |
| 10742150 | auto-Bilirubin-T liquicolor | Others |
| 10742300 | auto-Bilirubin-T liquicolor | Others |
| 10742600 | auto-Bilirubin-T liquicolor | Others |
| 10751 | Hemoglobin liquicolor | Others |
| 10770 | HbA1c liquidirect | Others |
| 10770600 | HbA1c liquidirect | Others |
| 10775 | HbA1c liquidirect, Control Set | Others |
| 10776 | HbA1c liquidirect, Calibrator Set | Others |
| 10786 | Glucose liquiUV Mono | Others |
| 11101 | Apo A1 | Others |
| 11101600 | Apolipoprotein A1 (APO A1) | Others |
| 11102 | Apo B | Others |
| 11102600 | Apolipoprotein B (APO B) | Others |
| 11104 | Apo A1/B Standard | Others |
| 11105 | Lp(a) | Others |
| 11105600 | Lp(a) | Others |
| 11107 | Lp(a) Standard | Others |
| 11110 | Complement C3 | Others |
| 11110600 | Complement C3 | Others |
| 11113 | Complement C4 | Others |
| 11113600 | Complement C4 | Others |
| 11115 | Transferrin | Others |
| 11115600 | Transferrin | Others |
| 11117 | C3/C4/TRF Standard | Others |
| 11120 | Microalbumin | Others |
| 11120600 | Microalbumin | Others |
| 11124 | Microalbumin Standard | Others |
| 11140 | Homocysteine liquiUV | Others |
| 11140600 | Homocysteine liquiUV | Others |
| 11141 | CRP Buffer | Others |
| 11143 | Homocysteine liquiUV Control Set | Others |
| 11145 | Homocysteine liquiUV Calibrator Set | Others |
| 11150 | Cystatin-C liquidirect | Others |
| 11150600 | Cystatin-C liquidirect | Others |
| 11153 | Cystatin-C liquidirect Controls | Others |
| 11155 | Cystatin-C liquidirectCalibrators | Others |
| 11241 | CRP | Others |
| 11241600 | C-Reactive Protein (CRP) | Others |
| 11251300 | Anti-Streptolysin-O | Others |
| 11251600 | Anti-Streptolysin-O | Others |
| 11251P | ASO Reagent Kit | Others |
| 11261P | RF Reagent Kit | Others |
| 11261300 | Rheumatoid Factors | Others |

| Cat.-no. | Product name | Class |
|----------|--|--------|
| 11261600 | Rheumatoid Factors | Others |
| 11261PA | RF Reagent Kit | Others |
| 11341 | CRP Standard | Others |
| 11351 | ASO Standard | Others |
| 11361 | RF Standard | Others |
| 11501 | Immunglobulins direct IgA direct Reagent kit | Others |
| 11501600 | Immunoglobulin A direct | Others |
| 11502 | Immunglobulins direct IgG direct Reagent kit | Others |
| 11502600 | Immunoglobulin G direct | Others |
| 11503 | Immunglobulins direct IgM direct Reagent kit | Others |
| 11503600 | Immunoglobulin M direct | Others |
| 11504 | Immunglobulins direct IgG ,IgA, IgM Calibrator Set | Others |
| 11505 | Immunglobulins direct Buffer | Others |
| 11610 | Ferritin Reagent Kit | Others |
| 11610600 | Ferritin | Others |
| 11614 | Ferritin Calibrator | Others |
| 12005 | CK NAC M-Test | Others |
| 12006 | Lipase liquicolor | Others |
| 12006600 | Lipase liquicolor | Others |
| 12007 | Cholinesterase liquicolor | Others |
| 12007300 | Cholinesterase liquicolor | Others |
| 12008 | CK-MB NAC M-Test | Others |
| 12009 | Pancreas Amylase liquicolor | Others |
| 12009600 | Pancreas-Amylase liquicolor | Others |
| 12011 | GOT(ASAT) liquiUV | Others |
| 12012 | GPT(ALAT) liquiUV | Others |
| 12013 | gamma-GT liquicolor | Others |
| 12014 | LDH SCE mod. liquiUV | Others |
| 12014150 | LDH SCE mod. liquiUV | Others |
| 12014300 | LDH SCE mod. liquiUV | Others |
| 12014600 | LDH SCE mod. liquiUV | Others |
| 12015 | CK NAC liquiUV | Others |
| 12015150 | CK NAC liquiUV | Others |
| 12015600 | CK-NAC liquiUV | Others |
| 12017 | Alk.Phosphatase liquicolor | Others |
| 12018 | Alpha-Amylase liquicolor | Others |
| 12021 | GOT (ASAT) IFCC mod. liquiUV | Others |
| 12021150 | GOT (ASAT) IFCC mod. liquiUV | Others |
| 12021300 | GOT (ASAT) IFCC mod. liquiUV | Others |
| 12021600 | GOT (ASAT) IFCC mod. liquiUV | Others |
| 12022 | GPT(ALAT) IFCC mod. liquiUV | Others |
| 12022150 | GPT(ALAT) IFCC mod. liquiUV | Others |
| 12022300 | GPT(ALAT) IFCC mod. liquiUV | Others |
| 12022600 | GPT(ALAT) IFCC mod. liquiUV | Others |
| 12023 | gamma GT liquicolor | Others |
| 12023150 | gamma GT liquicolor | Others |
| 12023300 | gamma GT liquicolor | Others |
| 12023600 | gamma GT liquicolor | Others |



| Cat.-no. | Product name | Class |
|-----------|--------------------------------------|--------|
| 12024 | LDH liquiUV | Others |
| 12026 | Lipase liquicolor | Others |
| 12027 | Alkaline Phosphatase liquicolor | Others |
| 12027150 | Alkaline Phosphatase liquicolor | Others |
| 12027300 | Alkaline Phosphatase opt. liquicolor | Others |
| 12027600 | Alkaline Phosphatase opt. liquicolor | Others |
| 12028 | alpha-Amylase liquicolor | Others |
| 12028150 | alpha-Amylase liquicolor | Others |
| 12028300 | alpha-Amylase liquicolor | Others |
| 12028600 | alpha-Amylase liquicolor | Others |
| 12029 | Pancreas Amylase liquicolor | Others |
| 12031 | GOT(ASAT) liquiUV | Others |
| 12032 | GPT(ALAT) liquiUV | Others |
| 12033 | Gamma-GT liquicolor | Others |
| 12037 | Alkaline Phosphatase liquicolor | Others |
| 12117 | Alkaline Phosphatase liquicolor IFCC | Others |
| 12117300 | Alkaline Phosphatase liquicolor IFCC | Others |
| 12117600 | Alkaline Phosphatase liquicolor IFCC | Others |
| 12118 | CK MB liquiUV | Others |
| 12118150 | CK MB liquiUV | Others |
| 12118600 | CK-MB liquiUV | Others |
| 12211 | GOT(ASAT) liquiUV M-Test | Others |
| 12212 | GPT(ALAT) liquiUV M-Test | Others |
| 12213 | Gamma-GT liquicolor M-Test | Others |
| 12214 | LDH liquiUV M-Test | Others |
| 12217 | Alk.Phos.liquicolor M-Test | Others |
| 12218 | Alpha-Amylase liquicolor M-Test | Others |
| 12290 | Iron TPTZ liquicolor | Others |
| 12290150 | Iron TPTZ liquicolor | Others |
| 12290300 | Iron TPTZ liquicolor | Others |
| 12290600 | Iron TPTZ liquicolor | Others |
| 12291 | Iron TPTZ liquicolor | Others |
| 12660 | Acid Phosphatase Humazym | Others |
| 13010 | TURBIDOS | Others |
| 13020600 | Ferritin Calibrator 500 | Others |
| 13151 | Serodos Plus | Others |
| 13160 | Autocal | Others |
| 13511 | Humatrol N | Others |
| 13512 | Humatrol P | Others |
| 13611 | CK-MB Control | Others |
| 13612 | CK-MB Calibrator | Others |
| 13951 | Serodos | Others |
| 15024 | HumaSRate | Others |
| 15024/40 | HSRate Control | Others |
| 15500 | HumaxHCT (220V) | Others |
| 15500/110 | HumaxHCT (110V) | Others |
| 15501 | Haematocrit rotor | Others |
| 156004 | Albumin liquicolor | Others |

| Cat.-no. | Product name | Class |
|----------|------------------------------|--------|
| 157004 | Total Protein liquicolor | Others |
| 15650 | HumaClot Duo ^{plus} | Others |
| 15660 | HumaClot Quattro | Others |
| 15800 | HumaClot Pro | Others |
| 15800/20 | HumaClot Pro – Wash Solution | Others |
| 15800/30 | HumaClot Pro – Cleaner | Others |
| 15910 | HumaCLIA 150 | Others |
| 16001/03 | Micro Cuvettes Hb | Others |
| 16070 | HumaMeter Hb ^{plus} | Others |
| 16070/1 | Reagent Hb | Others |
| 16070/25 | | |
| 16070/2 | Calibrator Set Hb | Others |
| 16070/3 | Control Set Hb | Others |
| 16080 | HumaMeter A1c | Others |
| 16085/50 | HumaMeter A1c Reagent Kit | Others |
| 16086 | HumaMeter A1c Control Kit | Others |
| 16180 | HumaNex A1c | Others |
| 16185 | HumaNex A1c Reagent Kit | Others |
| 16300 | ELISYS QUATTRO | Others |
| 16350/10 | HC5-Basolyse | Others |
| 16350/20 | HC5-Eolyse | Others |
| 16350/40 | HC5-Control | Others |
| 16420/30 | HumaCount 30 ^{TS} | Others |
| 16420/80 | HumaCount 80 ^{TS} | Others |
| 16430 | HumaCount 5L | Others |
| 16430/10 | Automatic Sample Loader | Others |
| 16430/20 | HC5L-Diluent | Others |
| 16430/30 | HC5L-Lyse | Others |
| 16430/40 | HC5L-Diff | Others |
| 16430/50 | HC5L-Control | Others |
| 16450 | HumaCount 5D | Others |
| 16450/10 | HC5D Diluent | Others |
| 16450/20 | HC5D CBC Lyse | Others |
| 16450/30 | HC5D Diff Lyse | Others |
| 16450/40 | HC5D Control | Others |
| 16450/60 | HC5D Clean | Others |
| 16670 | Humareader HS | Others |
| 16660 | HumaStar 600 | Others |
| 16660/11 | ISE Cleaner | Others |
| 16660/12 | ISE Conditioner | Others |
| 16660/13 | ISE Urine Diluent | Others |
| 16660/14 | ISE Standard Pack | Others |
| 16661/01 | Chimney | Others |
| 16663/10 | Diluent | Others |
| 16663/11 | Diluent-2 | Others |
| 16663/20 | Cuvette Clean | Others |
| 16663/25 | Tip Cleaning Kit | Others |
| 16700 | Humalyzer 3000 | Others |
| 16800 | Humalyzer 3500 | Others |
| 16880 | HumaStar 80 | Others |



| Cat.-no. | Product name | Class |
|-----------|---|--------|
| 16890 | HumaStar 100 | Others |
| 16895 | HumaStar 200 | Others |
| 16930 | HumaStar 300SR | Others |
| 16923/20 | Cuvette Clean | Others |
| 17200 | ELISYS DUO | Others |
| 17350 | ELISYS UNO | Others |
| 17400/10 | HC-Diluent | Others |
| 17400/11 | HC-Diluent | Others |
| 17400/20 | HC-Lyse CF | Others |
| 17400/22 | HC-Lyse CF | Others |
| 17400/30 | HC-Cleaner | Others |
| 17400/31 | HC-Cleaner | Others |
| 17400/40 | HC-Control | Others |
| 17400/50 | HC-Calibrator | Others |
| 17470/10 | HumaLyte Plus ³ | Others |
| 17470/20 | HumaLyte Plus ⁵ | Others |
| 17470/11 | K Electrode | Others |
| 17470/12 | Na Electrode | Others |
| 17470/13 | Cl Electrode | Others |
| 17470/14 | Ca Electrode | Others |
| 17470/15 | pH Electrode | Others |
| 17470/17 | Reference Electrode | Others |
| 17470/70 | QC Solution | Others |
| 17470/71 | Daily Cleaning Solution | Others |
| 17470/72 | Weekly Cleaning Solution | Others |
| 17470/74 | K Filling Solution | Others |
| 17470/75 | pH / Na / Cl Filling Solution | Others |
| 17470/76 | Ca Filling Solution | Others |
| 17470/78 | Reference Filling Solution | Others |
| 17470/79 | Na Conditioner | Others |
| 17470/82 | Reagent Pack HumaLyte Plus ³ | Others |
| 17470/83 | Reagent Pack HumaLyte Plus ⁵ | Others |
| 17470/86 | Urine Diluent | Others |
| 17470/110 | QC Solution | Others |
| 17546 | HumaSens ^{plus} Uric Acid Test Strips | Others |
| 17546/10 | HumaSens ^{plus} Uric Acid Control Solution normal | Others |
| 17547 | HumaSens ^{plus} Total Cholesterol Test Strips | Others |
| 17547/10 | HumaSens ^{plus} Total Cholesterol Control Solution normal | Others |
| 17560 | HumaSens 2.0 Starter Pack | II,B |
| 17561 | HumaSens 2.0 ^{plus} Starter Pack | Others |
| 17562 | Glucose Test Strips Blue HumaSens2.0/ HumaSens2.0 ^{plus} / HumaSens/HumaSens ^{plus} | II,B |
| 17562/2 | Glucose Test Strips Blue HumaSens2.0/ HumaSens2.0 ^{plus} / HumaSens/HumaSens ^{plus} | II,B |
| 17562/10 | Glucose Control HumaSens* / HumaSens ^{plus} * / HumaSens 2.0 / HumaSens2.0 ^{plus} (*BLUE GLU strip) | II/B |
| 17566 | Uric Acid Test Strips HumaSens 2.0 ^{plus} | Others |
| 17566/10 | Uric Acid Control Solution HumaSens 2.0 ^{plus} | Others |
| 17567 | Total Cholesterol Test Strips | Others |

| Cat.-no. | Product name | Class |
|----------|---|--------|
| | HumaSens 2.0 ^{plus} | |
| 17567/10 | Total Cholesterol Control Solution HumaSens 2.0 ^{plus} | Others |
| 17600 | Combilyzer ¹³ | Others |
| 18000 | HumaReader Single ^{plus} | Others |
| 18200 | HumaLyzer Primus | Others |
| 18222 | Flow Cell Cleaner | Others |
| 18250 | HumaLyzer 4000 | Others |
| 18300 | HumaLyzer 2000 | Others |
| 18460 | CombiWash | Others |
| 18680 | Humaclot Junior | Others |
| 18971 | Wash Additive | Others |
| 18973 | Cuvette Clean | Others |
| 18974 | Special Wash Solution | Others |
| 18974/2 | Special Wash Solution-2 | Others |
| 19110L | Humapette Smart Line 0.5 – 10µl | Others |
| 19120L | Humapette Smart Line 5 – 50µl | Others |
| 19125L | Humapette Smart Line 10 – 100µl | Others |
| 19130L | Humapette Smart Line 20 – 200µl | Others |
| 19140L | Humapette Smart Line 100 – 1000µl | Others |
| 19150L | Humapette Smart Line 1000 – 5000µl | Others |
| 19500L | Humapette Smart Line 5µl | Others |
| 19505L | Humapette Smart Line 10µl | Others |
| 19510L | Humapette Smart Line 20µl | Others |
| 19515L | Humapette Smart Line 25µl | Others |
| 19520L | Humapette Smart Line 50µl | Others |
| 19525L | Humapette Smart Line 100µl | Others |
| 19530L | Humapette Smart Line 200µl | Others |
| 19535L | Humapette Smart Line 250µl | Others |
| 19540L | Humapette Smart Line 500µl | Others |
| 19545L | Humapette Smart Line 1000µl | Others |
| 19110P | HumaPette Digital 0.5-10µl | Others |
| 19120P | HumaPette Digital 2-20µl | Others |
| 19125P | HumaPette Digital 10-100µl | Others |
| 19130P | HumaPette Digital 20-200µl | Others |
| 19140P | HumaPette Digital 100-1000µl | Others |
| 19150P | HumaPette Digital 0.5-5.0ml | Others |
| 19160P | HumaPette Digital 1.0-10.0ml | Others |
| 19320P | HumaPette Transfer-8 5-50µl | Others |
| 19330P | HumaPette Transfer-8 30-300µl | Others |
| 19505P | HumaPette Typ Fix 10µl | Others |
| 19510P | HumaPette Typ Fix 20µl | Others |
| 19515P | HumaPette Typ Fix 25µl | Others |
| 19520P | HumaPette Typ Fix 50µl | Others |
| 19525P | HumaPette Typ Fix 100µl | Others |
| 19530P | HumaPette Typ Fix 200µl | Others |
| 19540P | HumaPette Typ Fix 500µl | Others |
| 19545P | HumaPette Typ Fix 1000µl | Others |

| Cat.-no. | Product name | Class |
|-------------------|-------------------------------------|--------|
| 54025 | ft4 ELISA | Others |
| 54030 | TSH ELISA | Others |
| 55010 | Testosterone ELISA | Others |
| 55020 | Progesterone ELISA | Others |
| 55030 | Estradiol ELISA | Others |
| 55040 | Estriol ELISA | Others |
| 55050 | Cortisol ELISA | Others |
| 55060 | DHEA-S ELISA | Others |
| 55500 | 25-OH Vitamin D | Others |
| 57002P, 57004P | Hexagon HIV | II, A |
| 573351 | Sodium rapid | Others |
| 58002 | Hexagon Chagas | Others |
| 58012 | Hexagon Chlamydia | II, B |
| 58022 | Hexagon H.Pylori | Others |
| 58032 | HEXAGON TB | Others |
| 58042 | Hexagon Syphilis | Others |
| 58054 | Hexagon Malaria | Others |
| 58062 | HEXAGON Strep A | Others |
| 58082 | HEXAGON Dengue | Others |
| 58912 | Hexagon Chlamydia Collect | II, B |
| 60022 | Fertitex Mono | Others |
| 68004 | HumaPreg ^{Urine} | Others |
| 68902, 68932 | Hexagon hCG 1-Step ^{Urine} | Others |
| 71012 | HumaType Anti-A | II, A |
| 71022 | HumaType Anti-B | II, A |
| 71032 | HumaType Anti-A,B | II, A |
| 71042 | HumaType Anti-D IgM | II, A |
| 71052 | HumaType Anti-D IgM/IgG | II, A |
| 71062 | HumaType Anti-Human Globulin | II, B |
| 71072 | HumaType Albumin 22% | Others |
| 73005/12 | HumaTube No Additive (Z) | Others |
| 73020/12 | HumaTube Serum C/A (Z) | Others |
| 73023/12 | HumaTube Serum C/A (Z) | Others |
| 73030/12 | HumaTube Serum Gel-C/A (Z) | Others |
| 73032/12 | HumaTube K2-EDTA (K2E) | Others |
| 73040/12 | HumaTube K3-EDTA (K3E) | Others |
| 73045/12 | HumaTube K3-EDTA (K3E) | Others |
| 73050/12 | HumaTube Li-Heparin (LH) | Others |
| 73060/12 | HumaTube Na-Citrate 3.2 % (9NC) | Others |
| 73070/12 | HumaTube Glucose (FH) | Others |
| 961000 | HumaLoop T | Others |
| 962000 | HumaLoop M | Others |
| 963100 | HumaTurb A | Others |
| 963200 | HumaTurb C + A | Others |
| 964000 | HumaHeat | Others |
| ITC02850 | HumaScan | Others |
| ITC30500 | IMTEC-Gliadin-Antibodies IgG | Others |
| ITC30505 | IMTEC-d-Gliadin-Antibodies IgG | Others |
| ITC30600 | IMTEC-Gliadin-Antibodies IgA | Others |
| ITC30605 | IMTEC-d-Gliadin-Antibodies IgA | Others |

| Cat.-no. | Product name | Class |
|----------|--|--------|
| ITC30701 | IMTEC-Gastro-LIA | Others |
| ITC40040 | IMTEC-Salmononella-Antibodies Screen (cut-off) | Others |
| ITC40050 | IMTEC-Salmononella-Antibodies IgA (cut-off) | Others |
| ITC59001 | IMTEC-DsDNA-Antibodies | Others |
| ITC59002 | IMTEC-Nucleosome-Antibodies | Others |
| ITC59005 | IMTEC-ssDNA-Antibodies | Others |
| ITC59011 | IMTEC-Phosphatidylserine-Antibodies IgG | Others |
| ITC59021 | IMTEC-Phosphatidylserine-Antibodies IgM | Others |
| ITC59022 | IMTEC-Phosphatidylserine-Antibodies Combi | Others |
| ITC59027 | IMTEC-Phosphatidylserine-Antibodies Screen | Others |
| ITC59030 | IMTEC-CIC Screen (cut-off) | Others |
| ITC59031 | IMTEC-CIC IgG | Others |
| ITC59032 | IMTEC-C3d-CIC | Others |
| ITC59033 | IMTEC-Anti-C1q-Antibodies | Others |
| ITC59035 | IMTEC-Complement Activity | Others |
| ITC59050 | IMTEC-beta2-Glycoprotein 1-Antibodies Screen | Others |
| ITC59070 | IMTEC-Phospholipid-Antibodies Screen | Others |
| ITC59071 | IMTEC-Cardiolipin-Antibodies IgG | Others |
| ITC59076 | IMTEC-Cardiolipin-Antibodies Screen | Others |
| ITC59081 | IMTEC-Cardiolipin-Antibodies IgM | Others |
| ITC59082 | IMTEC-Cardiolipin-Antibodies Combi | Others |
| ITC59150 | IMTEC-beta2-Glycoprotein 1-Antibodies IgG | Others |
| ITC59250 | IMTEC-beta2-Glycoprotein 1-Antibodies IgM | Others |
| ITC59400 | IMTEC-Phosphatidylethanolamine-Antibodies Screen | Others |
| ITC59450 | IMTEC-Prothrombin-Antibodies Screen | Others |
| ITC59500 | IMTEC-oxLDL-Antibodies Ig(GM) | Others |
| ITC59550 | IMTEC-Annexin V-Antibodies Screen | Others |
| ITC60000 | IMTEC-RF Screen | Others |
| ITC60001 | IMTEC-ANA Screen | Others |
| ITC60003 | IMTEC-RF IgM | Others |
| ITC60005 | IMTEC-ENA Screen | Others |
| ITC60007 | IMTEC-RF IgG | Others |
| ITC60010 | IMTEC-RF IgA | Others |
| ITC60015 | IMTEC-RA33-Antibodies | Others |
| ITC60021 | IMTEC-CCP-Antibodies | Others |
| ITC60029 | IMTEC-SmD1-Antibodies IgG | Others |
| ITC60031 | IMTEC-Histone-Antibodies | Others |
| ITC60033 | IMTEC-ENA Profile | Others |
| ITC60040 | IMTEC-AMA M2 | Others |
| ITC60200 | IMTEC-Myositis LIA | Others |
| ITC60201 | IMTEC-Myositis LIA PL | Others |
| ITC66005 | IMTEC-Liver Screen S | Others |
| ITC66040 | IMTEC-Sp100-Antibodies | Others |
| ITC66050 | IMTEC-LKM1-Antibodies | Others |



| Cat.-no. | Product name | Class |
|----------|--------------------------------|--------|
| ITC66060 | IMTEC-SLA Antikörper (cut-off) | Others |
| ITC66205 | IMTEC-Liver-LIA S | Others |
| ITC70001 | IMTEC-ANA Screen (cut-off) | Others |
| ITC70005 | IMTEC-ENA Screen (cut-off) | Others |
| ITC70022 | IMTEC-U1-snRNP-Antibodies | Others |
| ITC70024 | IMTEC-SS-B/La-Antibodies | Others |
| ITC70025 | IMTEC-Jo1-Antibodies | Others |
| ITC70026 | IMTEC-SS-A/Ro-Antibodies | Others |
| ITC70028 | IMTEC-Scl70-Antibodies | Others |
| ITC80000 | HumaBlot 44 ^{FA} | Others |
| ITC82020 | IMTEC-PR3-ANCA | Others |
| ITC82030 | IMTEC-MPO-ANCA | Others |
| ITC82040 | IMTEC-Vasculitis-LIA | Others |

| Cat.-no. | Product name | Class |
|------------|-------------------------------|--------|
| ITC82070 | IMTEC-GBM-Antibodies | Others |
| ITC85010 | IMTEC-TG-Antibodies | Others |
| ITC85020 | IMTEC-TPO-Antibodies | Others |
| ITC85030 | IMTEC-TSH Receptor-Antibodies | Others |
| ITC92000 | IMTEC-ANA-LIA | Others |
| ITC92000-1 | IMTEC-ANA-LIA | Others |
| ITC92000-2 | IMTEC-ANA-LIA | Others |
| ITC92000-3 | IMTEC-ANA-LIA | Others |
| ITC92000-4 | IMTEC-ANA-LIA | Others |
| ITC92000-5 | IMTEC-ANA-LIA | Others |
| ITC92005 | IMTEC-ANA-LIA Maxx | Others |

Class: acc. to directive 98/79 EC

II, A = test listed in annex II, list A

II, B = test listed in annex II, list B

H = test for home use, not listed in annex II

Others

