

## AUTHORIZATION LETTER

We, **HUMAN Gesellschaft für Biochemica und Diagnostica mbH** (hereinafter called "**HUMAN**"), Max - Planck - Ring 21, 65205 Wiesbaden, Germany, hereby certify that company

**"Echipamed Plus" SRL**  
Valea Trandafirilor 24 <B>,  
2001 Chisinau  
Moldova

is our exclusive representative for HUMAN / IMTEC products in the territory of Moldova.

Echipamed Plus is therefore authorized to import, stock, market and sell HUMAN labeled products throughout the territory of Moldova.

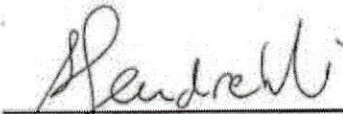
Echipamed Plus is also fully authorized to participate in official tenders and to provide installation, warranty service and maintenance for HUMAN equipment in the territory of Moldova.

Echipamed Plus is further authorized to submit applications on our behalf to the competent authority of Moldova for the registration and re-registration of HUMAN-labeled products in the name of HUMAN.

This Authorization Letter remains valid until 31.12.2024 and is only effective in connection with a valid Distribution Agreement.

Wiesbaden, 11 January 2024

**HUMAN Gesellschaft für Biochemica und Diagnostica mbH**

  
\_\_\_\_\_  
André Jendretzki  
International Sales Manager

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



## 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 D1030000083 and D1030000084).

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.: D1030000085, D1030000082, D1030000075, D1030000086 and D1030000068 respectively).

We further confirm in our sole responsibility that the IVD products listed in the attachments are designed, manufactured and controlled by us in accordance with the European Regulation 2017/746 on in vitro medical devices. Article 110 of this regulation is amended by EU Regulation 2022/112 establishing transitional periods for so called legacy products, which have already been CE-marked before May 26<sup>th</sup>, 2022 according to the European Directive 98/79. The transitional periods granted are: up to May 26<sup>th</sup>, 2025 for class D IVDs and for products covered by a certificate under 98/79/EC, up to May 26<sup>th</sup>, 2026 for class C IVDs and up to May 26<sup>th</sup>, 2027 for class B IVDs. Applicable conformity assessment procedures according to said regulations/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 that the products are either in conformity with the European Regulation 2017/746 (IVDs in attachment I) or continue to be in conformity with Directive 98/79/EC without any significant changes in the design and intended purpose (IVDS in attachment II). All IVD products also conform with the respective harmonized standards.

**Human**

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

HUMAN Gesellschaft für Biochemica und Diagnostica mbH

Date: 2023-02-24

Dr. Torsten Borchers  
Vice President Quality Assurance and Regulatory Affairs

**Attachment I - List of products which passed applicable conformity assessment procedures (article 48 of European Regulation 2017/746) by date of signing**

| Cat.-no.             | Product name                  | IVDR-Class | Basic UDI            |
|----------------------|-------------------------------|------------|----------------------|
| 11505                | IMMUNOGLOBULINS direct Buffer | A          | 04033145CC11505CS    |
| 40037                | GLYCINE-NaCl Buffer           | A          | 04033145RT40037U4    |
| 15500 /<br>15500/110 | HuMax HCT                     | A          | 04033145LQ15500PT    |
| 15650                | HumaClot Duo Plus             | A          | 04033145CO15650JU    |
| 15660                | HumaClot Quattro              | A          | 04033145CO15660JX    |
| 15800                | HumaClot Pro                  | A          | 04033145CO15800JP    |
| 15800/20             | HumaClot Pro Wash Solution    | A          | 04033145CO15800/20MA |
| 15800/30             | HumaClot Pro Cleaner          | A          | 04033145CO15800/30MD |
| 15910                | HumaCLIA 150                  | A          | 04033145CL15910HQ    |
| 16080                | HumaMeter A1c                 | A          | 04033145HG16080HT    |
| 16190                | HumaNex A1c Variant           | A          | 04033145HP16190MQ    |
| 16195                | HumaNex A1c Variant Reagent   | A          | 04033145HP16195N2    |
| 16300                | Elisys Quattro                | A          | 04033145EL16300HY    |
| 16430/20             | HC5L-Diluent                  | A          | 04033145HC16430/20H5 |
| 16430/30             | HC5L-Lyse                     | A          | 04033145HC16430/30H8 |
| 16430/40             | HC5L-Diff                     | A          | 04033145HC16430/40H8 |
| 16450/10             | HC5D-Diluent                  | A          | 04033145HC16450/10HQ |
| 16450/20             | HC5D-CBC-Lyse                 | A          | 04033145HC16450/20HT |
| 16450/30             | HC5D-Diff-Lyse                | A          | 04033145HC16450/30HW |
| 16450/60             | HC5D Clean                    | A          | 04033145HC16450/60J7 |
| 16660                | HumaStar 600                  | A          | 04033145CC16660EA    |
| 16661/01             | Chimney                       | A          | 04033145CC16661/01EJ |
| 16663/10             | Diluent                       | A          | 04033145CC16663/10EZ |
| 16663/11             | Diluent-2                     | A          | 04033145CC16663/11F3 |
| 16663/20             | Cuvette Clean                 | A          | 04033145CC18973FG    |
| 16663/25             | Tip Cleaning Kit              | A          | 04033145CC16663/25FE |
| 16670                | HumaReader HS                 | A          | 04033145EL16670K4    |
| 16890                | HumaStar 100                  | A          | 04033145CC16890EV    |
| 16895                | HumaStar 200                  | A          | 04033145CC16895F7    |
| 16930                | HumaStar 300 SR               | A          | 04033145CC16930EG    |
| 17200                | Elisys Duo                    | A          | 04033145EL17200J2    |
| 17350                | Elisys Uno                    | A          | 04033145EL17350JN    |
| 17400/11             | HC-Diluent                    | A          | 04033145HC17400/11GL |
| 17400/22             | HC-Lyse CF                    | A          | 04033145HC17400/22GR |
| 17400/31             | HC-Cleaner                    | A          | 04033145HC17400/31GS |
| 17400/55             | HC-Regular                    | A          | 04033145HC17400/55H8 |
| 17400/56             | HC-Acute                      | A          | 04033145HC17400/56HA |
| 17470/10             | HumaLyte Plus <sup>3</sup>    | A          | 04033145CC17470/10EE |
| 17470/20             | HumaLyte Plus <sup>5</sup>    | A          | 04033145CC17470/20EH |

| Cat.-no. | Product name                             | IVDR-Class | Basic UDI            |
|----------|------------------------------------------|------------|----------------------|
| 17470/71 | Daily Cleaning Solution                  | A          | 04033145CC17470/71F2 |
| 17470/72 | Weekly Cleaning Solution                 | A          | 04033145CC17470/72F4 |
| 17470/74 | K Filling Solution                       | A          | 04033145CC17470/74F8 |
| 17470/75 | pH / Na / Cl Filling Solution            | A          | 04033145CC17470/75FA |
| 17470/76 | Ca Filling Solution                      | A          | 04033145CC17470/76FC |
| 17470/78 | Reference Filling Solution               | A          | 04033145CC17470/78FG |
| 17470/79 | Na Conditioner                           | A          | 04033145CC17470/79FJ |
| 17470/86 | Urine Diluent                            | A          | 04033145CC17470/86FF |
| 17561    | HumaSens2.0 <sup>plus</sup> Starter Pack | A          | 04033145MM17561PS    |
| 17600    | Combilyzer <sup>13</sup>                 | A          | 04033145US17600VZ    |
| 18000    | HumaReader Single Plus                   | A          | 04033145EL18000HX    |
| 18200    | HumaLyzer Primus                         | A          | 04033145CC18200DJ    |
| 18222    | Flow Cell Cleaner                        | A          | 04033145CC18222DU    |
| 18250    | HumaLyzer 4000                           | A          | 04033145CC18250DZ    |
| 18460    | CombiWash                                | A          | 04033145EL18460K5    |
| 18680    | HumaClot Junior                          | A          | 04033145CO18680KS    |
| 18971    | Wash Additive                            | A          | 04033145CC18971FC    |
| 18973    | Cuvette Clean                            | A          | 04033145CC18973FG    |
| 18974    | Special Wash Solution                    | A          | 04033145CC18974FJ    |
| 18974/2  | Special Wash Solution-2                  | A          | 04033145CC18974/2E7  |
| 19130A   | AutoHumaPette 20-200µl                   | A          | 04033145LQ19130AQY   |
| 80050    | Pre-Trigger Solution HumaCLIA SR         | A          | 04033145CL80050HZ    |
| 80055    | Trigger Solution HumaCLIA SR             | A          | 04033145CL80055JB    |
| 80060    | Wash Buffer HumaCLIA SR                  | A          | 04033145CL80060J4    |
| 80110    | Sample Diluent B HumaCLIA SR             | A          | 04033145CL80110HS    |
| 961000   | HumaLoop T                               | A          | 04033145LO961000QN   |
| 962000   | HumaLoop M                               | A          | 04033145LO962000QV   |
| 963100   | HumaTurb A                               | A          | 04033145LO963100R9   |
| 963200   | HumaTurb C+A                             | A          | 04033145LO963100R9   |
| ITC80000 | HumaBlot 44 <sup>FA</sup>                | A          | 04033145LAITC80000PU |

**Attachment II – List of products which passed applicable conformity assessment procedures (annex III, annex IV of European Directive 98/79) by date of signing and benefit from the transition periods granted by regulation 2022/112**

| Cat.-no. | Product name                  | Class  |
|----------|-------------------------------|--------|
| 10010    | Magnesium liquicolor          | Others |
| 10010300 | Magnesium liquicolor          | Others |
| 10010600 | Magnesium liquicolor          | Others |
| 10011    | 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 |
| 10027300 | Phosphorus liquirapid         | Others |
| 10027600 | Phosphorus liquirapid         | Others |
| 10028    | Cholesterol liquicolor        | Others |
| 10028300 | Cholesterol liquicolor        | Others |
| 10028600 | Cholesterol liquicolor        | Others |
| 10051    | Creatinine liquicolor         | Others |
| 10052    | auto-Creatinine liquicolor    | Others |
| 10052300 | auto-Creatinine liquicolor    | Others |
| 10052600 | auto-Creatinine liquicolor    | Others |
| 10053    | Creatinine (Enzym) liquicolor | Others |
| 10053300 | Creatinine (Enzym) liquicolor | Others |
| 10053600 | Creatinine (Enzym) liquicolor | Others |
| 10084    | HDL Cholesterol liquicolor    | Others |
| 10084300 | HDL Cholesterol liquicolor    | Others |
| 10084600 | HDL Cholesterol liquicolor    | Others |
| 10094    | LDL Cholesterol liquicolor    | Others |
| 10094600 | LDL Cholesterol liquicolor    | Others |
| 10113    | Sodium liquicolor             | Others |
| 10113300 | Sodium liquicolor             | Others |
| 10113600 | Sodium liquicolor             | Others |
| 10114    | Sodium Standard               | Others |
| 10115    | Chloride liquicolor           | Others |
| 10115300 | Chloride liquicolor           | Others |
| 10118    | Potassium liquirapid          | Others |
| 10120    | Potassium liquiUV             | Others |
| 10120300 | Potassium liquiUV             | Others |
| 10120600 | Potassium liquiUV             | Others |
| 10121    | Glucose liquicolor            | Others |
| 10126    | Potassium Standard            | Others |
| 10229    | Iron liquicolor               | Others |

| Cat.-no.                  | Product name                             | Class  |
|---------------------------|------------------------------------------|--------|
| 10230                     | Iron liquicolor                          | Others |
| 10260                     | 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 |
| 10521300                  | Urea liquiUV                             | Others |
| 10521600                  | Urea liquiUV                             | Others |
| 10560                     | Albumin liquicolor                       | Others |
| 10560300                  | Albumin liquicolor                       | Others |
| 10560600                  | Albumin liquicolor                       | Others |
| 10570                     | 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,<br>10658,<br>10259 | Glycohemoglobin HbA <sub>1c</sub>        | Others |
| 10660                     | Acid Phosphatase Humazym                 | Others |
| 10660600                  | Acid Phosphatase                         | Others |
| 10670                     | TIBC                                     | Others |
| 10690                     | Uric acid liquicolor                     | Others |
| 10691                     | Uric acid liquicolor                     | Others |
| 10694                     | Uric acid liquicolor <sup>Plus</sup>     | Others |
| 10694300                  | Uric acid liquicolor <sup>Plus</sup>     | Others |
| 10694600                  | Uric acid liquicolor <sup>Plus</sup>     | Others |
| 10720P                    | Triglycerides liquicolor <sup>mono</sup> | Others |
| 10724                     | Triglycerides liquicolor <sup>mono</sup> | Others |
| 10724300                  | Triglycerides liquicolor <sup>mono</sup> | Others |
| 10724600                  | Triglycerides liquicolor <sup>mono</sup> | Others |
| 10725                     | Triglycerides liquicolor <sup>mono</sup> | Others |
| 10740                     | Bilirubin D&T liquicolor                 | Others |
| 10741                     | auto-Bilirubin-D liquicolor              | Others |
| 10741300                  | auto-Bilirubin-D liquicolor              | Others |
| 10741600                  | auto-Bilirubin-D liquicolor              | Others |
| 10742                     | auto-Bilirubin-T liquicolor              | Others |

| Cat.-no. | Product name                                 | Class  |
|----------|----------------------------------------------|--------|
| 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 |
| 11241300 | CRP                                          | Others |
| 11241600 | 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 |
| 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 |
| 11501300 | Immunoglobulins direct IgA                   | Others |
| 11501600 | Immunoglobulins direct IgA                   | Others |
| 11502    | Immunglobulins direct IgG direct Reagent kit | Others |

| Cat.-no. | Product name                                       | Class  |
|----------|----------------------------------------------------|--------|
| 11502300 | Immunoglobulins direct IgG                         | Others |
| 11502600 | Immunoglobulins direct IgG                         | Others |
| 11503    | Immunglobulins direct IgM direct Reagent kit       | Others |
| 11503300 | Immunoglobulins direct IgM                         | Others |
| 11503600 | Immunoglobulins direct IgM                         | Others |
| 11504    | Immunglobulins direct IgG, IgA, IgM Calibrator Set | 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 |
| 12014300 | LDH SCE mod. liquiUV                               | Others |
| 12014600 | LDH SCE mod. liquiUV                               | Others |
| 12015    | 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 |
| 12021300 | GOT (ASAT) IFCC mod. liquiUV                       | Others |
| 12021600 | GOT (ASAT) IFCC mod. liquiUV                       | Others |
| 12022    | 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 |
| 12023300 | gamma GT liquicolor                                | Others |
| 12023600 | gamma GT liquicolor                                | Others |
| 12024    | LDH liquiUV                                        | Others |
| 12026    | Lipase liquicolor                                  | Others |
| 12027    | Alkaline Phosphatase liquicolor                    | Others |
| 12027300 | Alkaline Phosphatase opt. liquicolor               | Others |
| 12027600 | Alkaline Phosphatase opt. Liquicolor               | Others |
| 12028    | alpha-Amylase liquicolor                           | Others |
| 12028300 | alpha-Amylase liquicolor                           | Others |
| 12028600 | alpha-Amylase liquicolor                           | Others |
| 12029    | Pancreas Amylase liquicolor                        | Others |
| 12031    | GOT(ASAT) liquiUV                                  | Others |

| Cat.-no. | Product name                            | Class  |
|----------|-----------------------------------------|--------|
| 12032    | GPT(ALAT) liquiUV                       | Others |
| 12033    | Gamma-GT liquicolor                     | Others |
| 12037    | Alkaline Phosphatase liquicolor         | Others |
| 12117    | Alkaline Phosphatase liquicolor<br>IFCC | Others |
| 12117300 | Alkaline Phosphatase liquicolor<br>IFCC | Others |
| 12117600 | Alkaline Phosphatase liquicolor<br>IFCC | Others |
| 12118    | CK-MB liquiUV                           | Others |
| 12118600 | CK-MB liquiUV                           | Others |
| 12127    | Alkaline Phosphatase liquicolor<br>IFCC | Others |
| 12137    | Alkaline Phosphatase liquicolor<br>IFCC | 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 |
| 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    | HumaSRate24 <sup>PT</sup>               | Others |
| 15024/40 | HSRate Control                          | Others |
| 156004   | Albumin liquicolor                      | Others |
| 157004   | Total Protein liquicolor                | Others |
| 16085/50 | HumaMeter A1c Reagent Kit               | Others |
| 16086    | HumaMeter A1c Control Kit               | Others |
| 16185    | HumaNex A1c Reagent Kit                 | Others |
| 16187    | HumaNex A1c Calibrator Kit              | Others |
| 16189    | HumaNex A1c Control Kit                 | Others |
| 16190/10 | HumaNex A1c Variant Column              | Others |
| 16197    | HumaNex A1c Variant Calibrator          | Others |
| 16199    | HumaNex A1c Variant Control             | Others |
| 16420/30 | HumaCount 30 <sup>TS</sup>              | Others |
| 16420/80 | HumaCount 80 <sup>TS</sup>              | Others |
| 16430    | HumaCount 5L                            | Others |
| 16430/10 | Automatic Sample Loader                 | Others |
| 16430/50 | HC5L-Control                            | Others |

| Cat.-no.                          | Product name                                                                                                                | Class  |
|-----------------------------------|-----------------------------------------------------------------------------------------------------------------------------|--------|
| 16450                             | HumaCount 5D                                                                                                                | Others |
| 16450/40                          | HC5D Control                                                                                                                | Others |
| 16451                             | HumaCount 5D <sup>CRP</sup>                                                                                                 | Others |
| 16451/40                          | CRP-Control HumaCount 5D <sup>CRP</sup>                                                                                     | Others |
| 16451/50                          | CRP-Calibrator HumaCount 5D <sup>CRP</sup>                                                                                  | Others |
| 16451/70                          | CRP-Reagent HumaCount 5D <sup>CRP</sup>                                                                                     | Others |
| 17400/40                          | HC-Control                                                                                                                  | Others |
| 17400/50                          | HC-Calibrator                                                                                                               | 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 |
| 17470/82                          | Reagent Pack HumaLyte Plus <sup>3</sup>                                                                                     | Others |
| 17470/83                          | Reagent Pack HumaLyte Plus <sup>5</sup>                                                                                     | Others |
| 17470/110                         | QC Solution                                                                                                                 | Others |
| 17560                             | HumaSens2.0 Starter Pack                                                                                                    | II,B   |
| 17562                             | Glucose Test Strips Blue<br>HumaSens2.0/ HumaSens2.0 <sup>plus</sup> /<br>HumaSens/HumaSens <sup>plus</sup>                 | II,B   |
| 17562/10                          | Glucose Control HumaSens* /<br>HumaSens <sup>plus</sup> * / HumaSens 2.0 /<br>HumaSens2.0 <sup>plus</sup> (*BLUE GLU strip) | II/B   |
| 17566                             | Uric Acid Test Strips HumaSens<br>2.0 <sup>plus</sup>                                                                       | Others |
| 17566/10                          | Uric Acid Control Solution<br>HumaSens 2.0 <sup>plus</sup>                                                                  | Others |
| 17567                             | Total Cholesterol Test Strips<br>HumaSens 2.0 <sup>plus</sup>                                                               | Others |
| 17567/10                          | Total Cholesterol Control Solution<br>HumaSens 2.0 <sup>plus</sup>                                                          | Others |
| 22102                             | Combina 10 M                                                                                                                | Others |
| 22132                             | Combina 13                                                                                                                  | Others |
| 23111                             | Combina 11 S                                                                                                                | Others |
| 27032P                            | Hexagon Troponin                                                                                                            | Others |
| 28009                             | Hexagon OBTI                                                                                                                | Others |
| 28009/2/12                        | Hexagon OBTI                                                                                                                | Others |
| 28021/1                           | Hexagon OBTI                                                                                                                | Others |
| 28024                             | Hexagon OBTI                                                                                                                | Others |
| 28025                             | Hexagon OBTI                                                                                                                | Others |
| 28032                             | Hexagon PSA                                                                                                                 | II, B  |
| 28220                             | Hexagon OBScreen                                                                                                            | Others |
| 29012                             | Hexagon IgE                                                                                                                 | Others |
| 31002,<br>31003                   | HemoStat Thromboplastin-SI                                                                                                  | Others |
| 31012                             | HemoStat Thromboplastin <sup>liquid</sup>                                                                                   | Others |
| 32002                             | HemoStat Fibrinogen                                                                                                         | Others |
| 33002,<br>33012<br>33013<br>33022 | HemoStat aPTT-EL                                                                                                            | Others |
| 34002                             | HemoStat Thrombin Time                                                                                                      | Others |

| Cat.-no.                                                                                                           | Product name                               | Class  |
|--------------------------------------------------------------------------------------------------------------------|--------------------------------------------|--------|
| 35001,<br>35002                                                                                                    | HemoStat Control Plasma (normal, abnormal) | Others |
| 35500                                                                                                              | HemoStat Calibrator                        | Others |
| 36002                                                                                                              | HemoStat D-Dimer                           | Others |
| 36003                                                                                                              | HemoStat D-Dimer                           | Others |
| 36012                                                                                                              | HemoStat D-Dimer Control high/low          | Others |
| 36102                                                                                                              | HemoStat Antithrombin liquid               | Others |
| 36201                                                                                                              | HemoStat free Protein S                    | Others |
| 40030,<br>40031                                                                                                    | SLE Latex Test                             | Others |
| 40037                                                                                                              | Glycin-NaCl buffer                         | Others |
| 40038                                                                                                              | IM Quick                                   | Others |
| 40042,<br>40043,<br>40040                                                                                          | Humatex CRP                                | Others |
| 40052,<br>40053,<br>40050                                                                                          | Humatex RF                                 | Others |
| 40063,<br>40060                                                                                                    | Humatex ASO                                | Others |
| 50001,<br>50002,<br>50016                                                                                          | Syphilis RPR                               | Others |
| 50101                                                                                                              | Syphilis TPHA liquid                       | Others |
| 50201,<br>50200,<br>50211,<br>50221,<br>50231,<br>50241,<br>50251,<br>50261,<br>50271,<br>50281,<br>50291<br>50301 | HUMATEX Febrile Antigens                   | Others |
| 51005                                                                                                              | Syphilis Screen                            | Others |
| 51015                                                                                                              | IgE total ELISA                            | Others |
| 51050                                                                                                              | HBsAg ultra sens                           | II, A  |
| 51103                                                                                                              | CMV IgM ELISA                              | II, B  |
| 51106                                                                                                              | Measles IgM ELISA                          | Others |
| 51107                                                                                                              | Mumps IgM ELISA                            | Others |
| 51108                                                                                                              | Rubella IgM $\mu$ -capture                 | II, B  |
| 51110                                                                                                              | VZV IgM ELISA                              | Others |
| 51119                                                                                                              | Toxo IgM $\mu$ -capture ELISA              | II, B  |
| 51126                                                                                                              | HSV IgM ELISA                              | Others |
| 51140                                                                                                              | Dengue IgM ELISA                           | Others |
| 51203                                                                                                              | CMV IgG ELISA                              | II, B  |
| 51206                                                                                                              | Measles IgG ELISA                          | Others |
| 51208                                                                                                              | Rubella IgG                                | II, B  |
| 51209                                                                                                              | Toxoplasma g. IgG ELISA                    | II, B  |
| 51210                                                                                                              | VZV IgG ELISA                              | Others |
| 51215                                                                                                              | HIV Ag/Ab ELISA                            | II, A  |

| Cat.-no.          | Product name                        | Class  |
|-------------------|-------------------------------------|--------|
| 51216             | HSV 1 IgG ELISA                     | Others |
| 51222             | H.Pylori IgG ELISA                  | Others |
| 51226             | HSV 2 IgG ELISA                     | Others |
| 51240             | Dengue IgG ELISA                    | Others |
| 51275             | Anti-HCV ELISA                      | II, A  |
| 51322             | H.Pylori IgA ELISA                  | Others |
| 52010             | AFP ELISA                           | Others |
| 52020             | CEA ELISA                           | Others |
| 52030             | PSA ELISA                           | II, B  |
| 52035             | fPSA ELISA                          | II, B  |
| 52050             | CA 125                              | Others |
| 52060             | CA 19-9                             | Others |
| 52080             | CA 15-3                             | Others |
| 53010             | LH ELISA                            | Others |
| 53020             | FSH ELISA                           | Others |
| 53030             | Prolactin ELISA                     | Others |
| 53040             | hCG ELISA                           | Others |
| 54010             | T3 ELISA                            | Others |
| 54015             | FT3 ELISA                           | Others |
| 54020             | T4 ELISA                            | Others |
| 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,<br>57004P | Hexagon HIV                         | II, A  |
| 573351            | Sodium rapid                        | Others |
| 58002             | Hexagon Chagas                      | Others |
| 58012             | Hexagon Chlamydia                   | II, B  |
| 58022             | Hexagon H.Pylori                    | Others |
| 58042             | Hexagon Syphilis                    | Others |
| 58054             | Hexagon Malaria                     | Others |
| 58062             | HEXAGON Strep A                     | Others |
| 58912             | Hexagon Chlamydia Collect           | II, B  |
| 68004             | HumaPreg <sup>Urine</sup>           | Others |
| 68902,<br>68932   | Hexagon hCG 1-Step <sup>Urine</sup> | Others |
| 82100             | HCG HumaCLIA SR                     | Others |
| 82105             | Progesterone HumaCLIA SR            | Others |
| 82110             | Testosterone HumaCLIA SR            | Others |
| 82115             | LH HumaCLIA SR                      | Others |
| 82120             | FSH HumaCLIA SR                     | Others |
| 82125             | Prolactin HumaCLIA SR               | Others |
| 82130             | Estradiol (E2) HumaCLIA SR          | Others |
| 82150             | AMH HumaCLIA SR                     | Others |

| Cat.-no. | Product name                                   | Class  |
|----------|------------------------------------------------|--------|
| 82850    | AMH Control HumaCLIA SR                        | Others |
| 83100    | AFP HumaCLIA SR                                | Others |
| 83105    | CEA HumaCLIA SR                                | Others |
| 83110    | CA 125 HumaCLIA SR                             | Others |
| 83115    | CA 15-3 HumaCLIA SR                            | Others |
| 83120    | CA 19-9 HumaCLIA SR                            | Others |
| 83125    | fPSA HumaCLIA SR                               | II, B  |
| 83130    | PSA HumaCLIA SR                                | II, B  |
| 84600    | TSH HumaCLIA SR                                | Others |
| 84605    | T4 HumaCLIA SR                                 | Others |
| 84610    | ft4 HumaCLIA SR                                | Others |
| 84615    | T3 HumaCLIA SR                                 | Others |
| 84620    | ft3 HumaCLIA SR                                | Others |
| 84625    | Anti-TG HumaCLIA SR                            | Others |
| 84630    | Anti-TPO HumaCLIA SR                           | Others |
| 84850    | Immunoassay Multi Control HumaCLIA SR          | Others |
| 85000    | 25-OH Vitamin D HumaCLIA SR                    | Others |
| 85020    | PCT HumaCLIA SR                                | Others |
| 85030    | Troponin I HumaCLIA SR                         | Others |
| 85035    | Myoglobin HumaCLIA SR                          | Others |
| 85040    | CK-MB HumaCLIA SR                              | Others |
| 85050    | Ferritin HumaCLIA SR                           | Others |
| 85055    | Vitamin B12 HumaCLIA SR                        | Others |
| 85820    | PCT Control HumaCLIA SR                        | Others |
| ITC30300 | IMTEC-t-Transglutaminase Antibodies IgG        | Others |
| ITC30400 | IMTEC-t-Transglutaminase Antibodies IgA        | Others |
| ITC30505 | IMTEC-d-Gliadin-Antibodies IgG                 | Others |
| ITC30605 | IMTEC-d-Gliadin-Antibodies IgA                 | Others |
| 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 |
| ITC59011 | IMTEC-Phosphatidylserine-Antibodies IgG        | Others |
| ITC59021 | IMTEC-Phosphatidylserine-Antibodies IgM        | Others |
| ITC59027 | IMTEC-Phosphatidylserine-Antibodies Screen     | 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 |

| Cat.-no.   | Product name                                     | Class  |
|------------|--------------------------------------------------|--------|
| 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 |
| ITC60001   | IMTEC-ANA Screen                                 | Others |
| ITC60003   | IMTEC-RF IgM                                     | Others |
| ITC60007   | IMTEC-RF IgG                                     | Others |
| ITC60015   | IMTEC-RA33-Antibodies                            | Others |
| ITC60021   | IMTEC-CCP-Antibodies                             | Others |
| ITC60029   | IMTEC-SmD1-Antibodies IgG                        | Others |
| ITC60033   | IMTEC-ENA Profile                                | Others |
| ITC60040   | IMTEC-AMA M2                                     | Others |
| ITC60201   | IMTEC-Myositis LIA PL                            | Others |
| ITC66050   | IMTEC-LKM1-Antibodies                            | 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 |
| ITC80001   | IMTEC-HumaScan <sup>FA</sup> Software            | Others |
| ITC80002   |                                                  |        |
| ITC80003   |                                                  |        |
| ITC80004   |                                                  |        |
| ITC82020   | IMTEC-PR3-ANCA                                   | Others |
| ITC82030   | IMTEC-MPO-ANCA                                   | Others |
| ITC82040   | IMTEC-Vasculitis-LIA                             | Others |
| 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 |
| ITC92007   | IMTEC-ANA-LIA XL                                 | Others |
| ITC94000   | IMTEC-Arthritis-LIA                              | 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

# 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

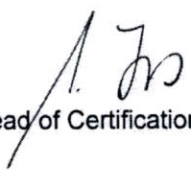
The mdc audit has proven that this quality management system  
meets all requirements of the following standard

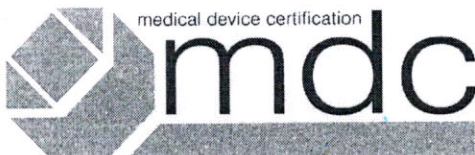
### EN ISO 9001

Quality management systems –  
Requirements

(ISO 9001:2015)

|                  |                  |
|------------------|------------------|
| Valid from       | 2022-03-12       |
| Valid until      | 2025-03-11       |
| Registration no. | D1030000083      |
| Report no.       | P21-01793-219728 |
| Stuttgart        | 2022-03-10       |

  
Head of Certification Body



mdc medical device certification GmbH  
Kriegerstraße 6  
D-70191 Stuttgart, Germany  
Phone: +49-(0)711-253597-0  
Fax: +49-(0)711-253597-10  
Internet: <http://www.mdc-ce.de>



# 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  
reagents, reagent products, calibrators and control materials for clinical chemistry,  
haematology, haemostasis, immune chemistry as well as analyzers for in-vitro diagnosis.  
distribution of test kits for molecular biology analyses as well as  
rapid tests for the diagnosis of infectious diseases.

has introduced and applies a

## Quality Management System

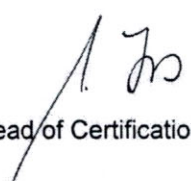
The mdc audit has proven that this quality management system  
meets all requirements of the following standard

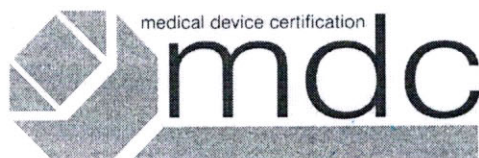
### EN ISO 13485

Medical devices – Quality management systems –  
Requirements for regulatory purposes

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

|                  |                  |
|------------------|------------------|
| Valid from       | 2022-03-12       |
| Valid until      | 2025-03-11       |
| Registration no. | D1030000084      |
| Report no.       | P21-01793-219732 |
| Stuttgart        | 2022-03-10       |

  
Head of Certification Body



mdc medical device certification GmbH  
Kriegerstraße 6  
D-70191 Stuttgart, Germany  
Phone: +49-(0)711-253597-0  
Fax: +49-(0)711-253597-10  
Internet: <http://www.mdc-ce.de>

