

## 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 31.12.2020 and is only effective in connection with a valid Distribution Agreement.

Wiesbaden, 23 January 2020

**HUMAN Gesellschaft für Biochemica und Diagnostica mbH**

  
Dhimitraq Jani  
International Sales Manager

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



# Certificate

**mdc medical device certification GmbH**  
certifies that

## Human

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

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

  
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  
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

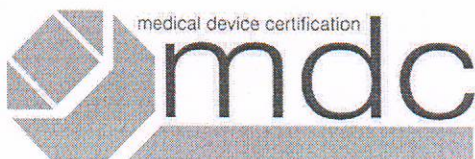
### EN ISO 13485

Medical devices – Quality management systems –  
Requirements for regulatory purposes

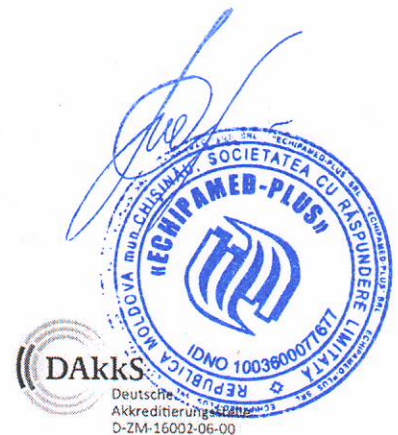
EN ISO 13485:2016 + AC:2016 - ISO 13485:2016

|                  |                  |
|------------------|------------------|
| 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



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>



## 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,<br>10658,<br>10259 | Glycohemoglobin HbA <sub>1c</sub>        | 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 <sup>plus</sup>     | Others |
| 10694150                  | 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 |





| Cat.-no. | Product name                             | Class  |
|----------|------------------------------------------|--------|
| 10724    | Triglycerides liquicolor <sup>mono</sup> | Others |
| 10724150 | 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 |
| 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(ALT) 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(ALT) 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 <sup>plus</sup> | 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 <sup>plus</sup> | 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 <sup>TS</sup>   | Others |
| 16420/80 | HumaCount 80 <sup>TS</sup>   | 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 |





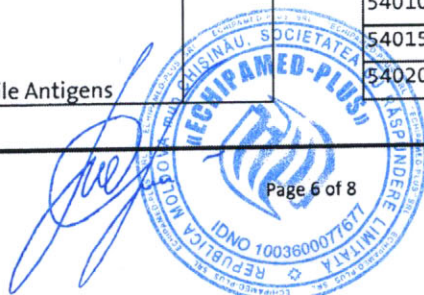
| Cat.-no.  | Product name                                                                                                          | Class  |
|-----------|-----------------------------------------------------------------------------------------------------------------------|--------|
| 16890     | HumaStar 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 <sup>3</sup>                                                                                            | Others |
| 17470/20  | HumaLyte Plus <sup>5</sup>                                                                                            | 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 <sup>3</sup>                                                                               | Others |
| 17470/83  | Reagent Pack HumaLyte Plus <sup>5</sup>                                                                               | Others |
| 17470/86  | Urine Diluent                                                                                                         | Others |
| 17470/110 | QC Solution                                                                                                           | Others |
| 17546     | HumaSens <sup>plus</sup> Uric Acid Test Strips                                                                        | Others |
| 17546/10  | HumaSens <sup>plus</sup> Uric Acid Control Solution normal                                                            | Others |
| 17547     | HumaSens <sup>plus</sup> Total Cholesterol Test Strips                                                                | Others |
| 17547/10  | HumaSens <sup>plus</sup> Total Cholesterol Control Solution normal                                                    | Others |
| 17560     | HumaSens 2.0 Starter Pack                                                                                             | II,B   |
| 17561     | HumaSens 2.0 <sup>plus</sup> Starter Pack                                                                             | Others |
| 17562     | Glucose Test Strips Blue HumaSens2.0/ HumaSens2.0 <sup>plus</sup> / HumaSens/HumaSens <sup>plus</sup>                 | II,B   |
| 17562/2   | Glucose Test Strips Blue HumaSens2.0/ HumaSens2.0 <sup>plus</sup> / HumaSens/HumaSens <sup>plus</sup>                 | II,B   |
| 17562/10  | Glucose Control HumaSens* / HumaSens <sup>plus</sup> * / HumaSens 2.0 / HumaSens2.0 <sup>plus</sup> (*BLUE GLU strip) | II/B   |
| 17566     | Uric Acid Test Strips HumaSens 2.0 <sup>plus</sup>                                                                    | Others |
| 17566/10  | Uric Acid Control Solution HumaSens 2.0 <sup>plus</sup>                                                               | Others |
| 17567     | Total Cholesterol Test Strips                                                                                         | Others |

| Cat.-no. | Product name                                                    | Class  |
|----------|-----------------------------------------------------------------|--------|
|          | HumaSens 2.0 <sup>plus</sup>                                    |        |
| 17567/10 | Total Cholesterol Control Solution HumaSens 2.0 <sup>plus</sup> | Others |
| 17600    | Combilyzer <sup>13</sup>                                        | Others |
| 18000    | HumaReader Single <sup>plus</sup>                               | 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  |
|----------------------------------------------------------|-----------------------------------------------|--------|
| 19550P                                                   | Starter Kit 10, 100, 1000 Digital             | Others |
| 19150/10                                                 | Pipette Tips 5 ml white                       | Others |
| 19160/10                                                 | Pipette Tips 10 ml white                      | Others |
| 19320/10                                                 | Pipette Tips 300 µl white                     | Others |
| 19320/20                                                 | Pipette Tips 20 µl crystal                    | Others |
| 19910/20                                                 | Pipette Tips 200 µl yellow                    | Others |
| 19920/40                                                 | Pipette Tips 1000 µl blue                     | Others |
| 22002                                                    | Combina 9SG                                   | Others |
| 22022                                                    | Combina 2                                     | Others |
| 22032                                                    | Combina 3                                     | Others |
| 22092                                                    | Combina Glucose                               | Others |
| 22102                                                    | Combina 10 M                                  | Others |
| 22132                                                    | Combina 13                                    | Others |
| 23111                                                    | Combina 11 S                                  | Others |
| 27032P                                                   | Hexagon Troponin                              | Others |
| 28009                                                    | 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 |
| 35001,<br>35002                                          | HemoStat Control Plasma<br>(normal, abnormal) | Others |
| 35500                                                    | HemoStat Calibrator                           | Others |
| 36002                                                    | HemoStat D-Dimer                              | Others |
| 36012                                                    | HemoStat D-Dimer Control<br>high/low          | Others |
| 36102                                                    | HemoStat Antithrombin liquid                  | Others |
| 40030,<br>40031                                          | SLE Latex Test                                | Others |
| 40037                                                    | Glycin-NaCl buffer                            | Others |
| 40038,<br>40039                                          | I.M. Quick                                    | Others |
| 40042,<br>40043,<br>40040                                | Humatex CRP                                   | Others |
| 40052,<br>40053,<br>40050                                | Humatex RF                                    | Others |
| 40062,<br>40063,<br>40060                                | Humatex ASO                                   | Others |
| 50001,<br>50002,<br>50016                                | Syphilis RPR                                  | Others |
| 50101                                                    | Syphilis TPHA                                 | Others |
| 50201,<br>50200,<br>50211,<br>50221,<br>50231,<br>50241, | HUMATEX Febrile Antigens                      | Others |

| Cat.-no.                                               | Product name              | Class  |
|--------------------------------------------------------|---------------------------|--------|
| 50251,<br>50261,<br>50271,<br>50281,<br>50291<br>50301 |                           |        |
| 51005                                                  | Syphilis Screen           | Others |
| 51015                                                  | IgE total ELISA           | Others |
| 51050                                                  | HBsAg ultra sens          | II, A  |
| 51103                                                  | CMV IgM ELISA             | II, B  |
| 51104                                                  | EBV IgM ELISA             | Others |
| 51106                                                  | Measles IgM ELISA         | Others |
| 51107                                                  | Mumps IgM ELISA           | Others |
| 51108                                                  | Rubella IgM µ-capture     | II, B  |
| 51110                                                  | VZV IgM ELISA             | Others |
| 51119                                                  | Toxo IgM µ-capture ELISA  | II, B  |
| 51126                                                  | HSV IgM ELISA             | Others |
| 51140                                                  | Dengue Virus IgM ELISA    | Others |
| 51150                                                  | Chagas Rec ELISA          | Others |
| 51203                                                  | CMV IgG ELISA             | II, B  |
| 51204                                                  | EBV IgG ELISA             | Others |
| 51205C                                                 | anti-HIV ½ ELISA          | II, A  |
| 51206                                                  | Measles IgG ELISA         | Others |
| 51207                                                  | Mumps 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  |
| 51216                                                  | HSV 1 IgG ELISA           | Others |
| 51222                                                  | H.Pylori IgG ELISA        | Others |
| 51226                                                  | HSV 2 IgG ELISA           | Others |
| 51228                                                  | Chlamydia Trachomatis IgG | II, B  |
| 51240                                                  | Dengue Virus IgG ELISA    | Others |
| 51275                                                  | Anti-HCV ELISA            | II, A  |
| 51322                                                  | H.Pylori IgA ELISA        | Others |
| 51328                                                  | Chlamydia Trachomatis IgA | II, B  |
| 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 |





| 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,<br>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 <sup>Urine</sup>           | Others |
| 68902,<br>68932   | Hexagon hCG 1-Step <sup>Urine</sup> | 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 <sup>FA</sup>      | 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

