

Human  
Gesellschaft für Biochemica  
und Diagnostica mbH

Max-Planck-Ring 21  
D-65205 Wiesbaden  
Germany

# Certificate

We, HUMAN GmbH, Max-Planck-Ring 21, 65 205 Wiesbaden, Germany,  
hereby certify that the company

## Echipamed Plus SRL

str. Valea Trandafirilor, 24B  
MD-2001, Chisinau  
Moldova

is the exclusive distributor of

## HUMAN GmbH

in the territory of Moldova Republic,  
effective by October 11, 2000.

Wiesbaden, February 21, 2007

HUMAN GmbH



**Ralph Neuberger**  
Director of Sales & Marketing

**Human**

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



## Compatibility of HUMAN coagulation reagents with HUMAN & non-HUMAN instruments

Wiesbaden, 9 January, 2017

We, HUMAN Gesellschaft für Biochemica und Diagnostica mbH, headquartered in Max-Planck-Ring 21, 65205 Wiesbaden, Germany, who are legal Manufacturers of in vitro diagnostic products, having factories at Stegelitzer Str. 3, 39126 Magdeburg, Germany,

do hereby confirm that all coagulation reagents manufactured by HUMAN can be processed manually and automatically. Coagulation reagents can be used on 'open' non-HUMAN automated analyzers, such as

- SYSMEX CA-560
- SYSMEX CA-660

Method settings for non-HUMAN instruments must be created by a qualified application specialist.

HUMAN Gesellschaft für Biochemica und Diagnostica mbH



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65205 Wiesbaden-Delkenheim  
Germany

Dhimitraq Jani  
International Sales Manager



Commerzbank AG  
BLZ 510 400 38  
Kto.-Nr. 716053400  
SWIFT-BIC: COBA DE FF 510  
IBAN: DE91 5104 0038 0716 0534 00

Norddeutsche Landesbank  
BLZ 250 500 00  
Kto.-Nr. 122 037 724  
SWIFT-BIC: NOLA DE 2H  
IBAN: DE76 2505 0000 0122 0377 24

Landesbank Baden-Württemberg  
BLZ 600 501 01  
Kto.-Nr. 263 6685  
SWIFT-BIC: SOLA DE ST600  
IBAN: DE93 6005 0101 0002 6366 85

Geschäftsführer:  
Ralph Neuberger  
Vorsitzender des Beirats:  
Dr. Thomas Guth

e-Mail [human@human.de](mailto:human@human.de)  
[www.human.de](http://www.human.de)  
ILN 40 33145 000006  
UST-IdNr.: DE113854181  
RG: Wiesbaden HRB 10782

# 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

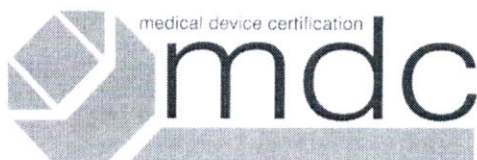
### EN ISO 9001

Quality management systems –  
Requirements

(ISO 9001:2015)

|                  |                  |
|------------------|------------------|
| Valid from       | 2019-03-12       |
| Valid until      | 2022-03-11       |
| Registration no. | D1030000072      |
| Report no.       | P18-01225-128826 |
| 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-c.de>



# Certificate

**mdc medical device certification GmbH**  
certifies that

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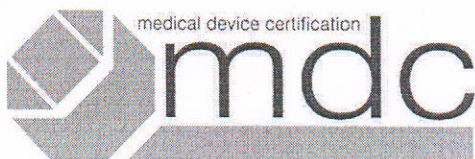
### EN ISO 13485

**Medical devices – Quality management systems –  
Requirements for regulatory purposes**

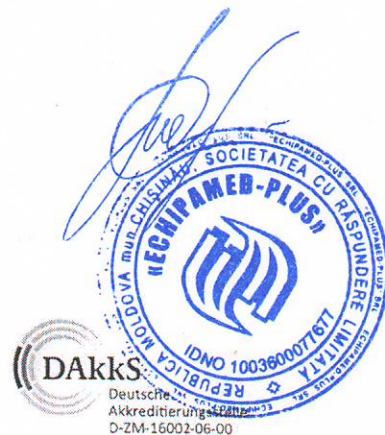
EN ISO 13485:2016 + AC:2016 - ISO 13485:2016

|                  |                  |
|------------------|------------------|
| 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  
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Phone: +49-(0)711-253597-0  
Fax: +49-(0)711-253597-10  
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## Declaration of Conformity



We,

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

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

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

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

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

HUMAN Gesellschaft für Biochemica und Diagnostica mbH

Date: November 01, 2019

Dr. Torsten Borchers  
Vice President Quality Assurance and Regulatory Affairs

**Human**

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

Attachment



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

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

| Cat.-no.                  | Product name                             | Class  |
|---------------------------|--|--------|
| 10120                     | Potassium liquiUV                        | Others |
| 10120150                  | Potassium liquiUV                        | Others |
| 10120300                  | Potassium liquiUV                        | Others |
| 10120600                  | Potassium liquiUV                        | Others |
| 10121                     | Glucose liquicolor                       | Others |
| 10126                     | Potassium Standard                       | Others |
| 10229                     | Iron liquicolor                          | Others |
| 10230                     | Iron liquicolor                          | Others |
| 10260                     | Glucose liquicolor                       | Others |
| 10260150                  | Glucose liquicolor                       | Others |
| 10260300                  | Glucose liquicolor                       | Others |
| 10260600                  | Glucose liquicolor                       | Others |
| 10284                     | HDL Cholesterol liquicolor               | Others |
| 10294                     | LDL Cholesterol liquicolor               | Others |
| 10505                     | Urea liquicolor                          | Others |
| 10506                     | Urea liquicolor R1                       | Others |
| 10507                     | Urea liquicolor R2                       | Others |
| 10521                     | Urea liquiUV                             | Others |
| 10521150                  | Urea liquiUV                             | Others |
| 10521300                  | Urea liquiUV                             | Others |
| 10521600                  | Urea liquiUV                             | Others |
| 10560                     | Albumin liquicolor                       | Others |
| 10560150                  | Albumin liquicolor                       | Others |
| 10560300                  | Albumin liquicolor                       | Others |
| 10560600                  | Albumin liquicolor                       | Others |
| 10570                     | Total Protein liquicolor                 | Others |
| 10570150                  | Total Protein liquicolor                 | Others |
| 10570300                  | Total Protein liquicolor                 | Others |
| 10570600                  | Total Protein liquicolor                 | Others |
| 10590                     | Urinary Total Protein liquicolor         | Others |
| 10590300                  | Urinary Total Protein liquicolor         | Others |
| 10595                     | Urinary Total Protein Standard           | Others |
| 10657,<br>10658,<br>10259 | Glycohemoglobin HbA <sub>1</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<br>HumaSens2.0/ HumaSens2.0 <sup>plus</sup> /<br>HumaSens/HumaSens <sup>plus</sup>                    | II,B   |
| 17562/2   | 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<br>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  | 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



# EC Declaration of Conformity

## Application of Directives:

- 98/79/EC of 27 October 1998 on In Vitro Diagnostic Medical Devices

## Means of conformity:

The following product is in conformity with

- Directive 98/79/EC based on the conformity assessment procedures in accordance with Annex III of the Directive.

## Product identification:

Product name: CA CLEAN I

Classification: Other device (except Annex II and self-testing devices)

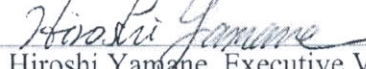
## List of Applied Standards:

- Harmonised Standards used for conformity assessment are listed in the technical documentation.

## Legal Manufacturer:

Name: SYSMEX CORPORATION

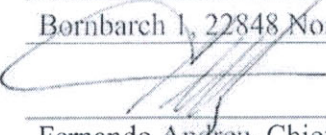
Address: 1-5-1 Wakinohama-Kaigandori, Chuo-ku, Kobe 651-0073, Japan

Authorised officer:  Date: 13 March 2018  
Hiroshi Yamane, Executive Vice President

## Authorised representative:

Name: SYSMEX EUROPE GMBH

Address: Bornbarch 1, 22848 Norderstedt, Germany

Authorised officer:  Date: MARCH 21<sup>ST</sup> 2018  
Fernando Andreu, Chief Operations Officer

This declaration of conformity is issued under the sole responsibility of the manufacturer and is valid until 25.05.2022 or until a revised declaration is Issued due to product modifications.

# EC Declaration of Conformity



## Application of Council Directive:

- 98/79/EC of 27 October 1998 on In Vitro Diagnostic Medical Devices

## Means of conformity:

The following products are in conformity with

- Directive 98/79/EC based on the conformity assessment procedures in accordance with Annex III,

## Product identification:

Product name: REACTION TUBE

Model name: SU-40

Classification: Other device (except Annex II and self-testing devices)

## List of Applied Standards:

- Harmonised Standards used for conformity assessment are listed in the technical documentation.

## Legal Manufacturer:

Name: SYSMEX CORPORATION

Address: 1-5-1 Wakinohama-Kaigandori, Chuo-ku, Kobe 651-0073 Japan

Authorised officer:

*Hiroshi Yamane*  
Hiroshi Yamane, Executive Vice President

Date:

*13 March, 2018*

## Authorised representative:

Name: SYSMEX EUROPE GMBH

Address: Bornbarch 1, 22848 Norderstedt, Germany

Authorised officer:

*Fernando Andreu*  
Fernando Andreu, Chief Operations Officer

Date:

*MARCH 21<sup>st</sup> 2018*

This declaration of conformity is issued under the sole responsibility of the manufacturer and is valid until 25.05.2022 or until a revised declaration is Issued due to product modifications.





# Zhejiang SKG Medical Technology Co., Ltd

Add: No.39, Anye Road, Gaoqiao Street, Huangyan, Taizhou, Zhejiang, China, 318020

Tel: 0086-576-84031666 Fax: 0086-576-84036668 Http://www.skgmed.com

## CE Declaration of Conformity

Manufacturer: Zhejiang SKG Medical Technology Co., Ltd.

NO.39 Anye Road, Gaoqiao Street, Huangyan 318020 Taizhou, Zhejiang

PEOPLE'S REPUBLIC OF CHINA

European

Representative: Shanghai International Holding corp. GmbH(Europe)

Eiffestrasse 80 20537 Hamburg GERMANY

Product Name: Sample Cup

Model Number: BS-200, 700

Classification (IVDD): Other

Conformity Assessment Route: IVDD Annex III

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

### DIRECTIVES

General applicable directives:

Medical Device Directive: Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices

Standard Applied:

ISO13485:2003, ISO11135-1:2007, ISO14971:2007, ISO 15223-1:2012

Notified Body: TÜV SÜD Product Service GmbH Zertifizierstelle Ridlerstraße 65·80339

München Germany

Identification number: Not applicable

(EC) Certificate(s): Not applicable

Expire date of the Certificate: Not applicable

Start of CE Marking: Not yet

Place, Date of Issue: HuangYan 2021-12-17

Signature: 

Name: Sujian

Position: General Manager

