

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 ,
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 31.12.2019 and is only effective in connection with a valid Distribution Agreement.

Wiesbaden, 7 February 2019

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-Delkenheim
Germany

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:
Lorenz von Schröder

e-Mail human@human.de
www.human.de
ILN 40 33145 000006
USt-IdNr.: DE113854181
RG: Wiesbaden HRB 10782



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.

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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
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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 13485:2012+AC:2012 – ISO 13485:2003 + Cor. 1:2009. 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 D1030000066 and D1030000030).

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.: D1030000067, D1030000028, D1030000032, 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: February 28, 2019

Dr. Torsten Borchers
Vice President Quality Assurance and Regulatory Affairs

Human

Gesellschaft für Biochemica
und Diagnostica mbH
Max-Planck-Ring 21
65205 Wiesbaden-Delkenheim
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
10052600	auto-Creatinine liquicolor	Others
10053	Creatinine (Enzym) liquicolor	Others
10053150	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
10120	Potassium liquiUV	Others
10120150	Potassium liquiUV	Others

Cat.-no.	Product name	Class
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
10521600	Urea liquiUV	Others
10560	Albumin liquicolor	Others
10560150	Albumin liquicolor	Others
10560300	Albumin liquicolor	Others
10560600	Albumin liquicolor	Others
10570	Total Protein liquicolor	Others
10570150	Total Protein liquicolor	Others
10570300	Total Protein liquicolor	Others
10570600	Total Protein liquicolor	Others
10590	Urinary Total Protein liquicolor	Others
10590300	Urinary Total Protein liquicolor	Others
10595	Urinary Total Protein Standard	Others
10657, 10658, 10259	Glycohemoglobin HbA _{1c}	Others
10660	Acid Phosphatase Humazym	Others
10660150	Acid Phosphatase	Others
10660600	Acid Phosphatase	Others
10670	TIBC	Others
10690	Uric acid liquicolor	Others
10691	Uric acid liquicolor	Others
10694	Uric acid liquicolor ^{plus}	Others
10694150	Uric acid liquicolor ^{plus}	Others
10694300	Uric acid liquicolor ^{plus}	Others
10694600	Uric acid liquicolor ^{plus}	Others
10720P	Triglycerides liquicolor ^{mono}	Others
10724	Triglycerides liquicolor ^{mono}	Others
10724150	Triglycerides liquicolor ^{mono}	Others
10724300	Triglycerides liquicolor ^{mono}	Others

Cat.-no.	Product name	Class
10724600	Triglycerides liquicolor ^{mono}	Others
10725	Triglycerides liquicolor ^{mono}	Others
10740	Bilirubin D&T liquicolor	Others
10741	auto-Bilirubin-D liquicolor	Others
10741150	auto-Bilirubin-D liquicolor	Others
10741300	auto-Bilirubin-D liquicolor	Others
10741600	auto-Bilirubin-D liquicolor	Others
10742	auto-Bilirubin-T liquicolor	Others
10742150	auto-Bilirubin-T liquicolor	Others
10742300	auto-Bilirubin-T liquicolor	Others
10742600	auto-Bilirubin-T liquicolor	Others
10751	Hemoglobin liquicolor	Others
10770	HbA1c liquidirect	Others
10770600	HbA1c liquidirect	Others
10775	HbA1c liquidirect, Control Set	Others
10776	HbA1c liquidirect, Calibrator Set	Others
10786	Glucose liquiUV Mono	Others
11101	Apo A1	Others
11101600	Apolipoprotein A1 (APO A1)	Others
11102	Apo B	Others
11102600	Apolipoprotein B (APO B)	Others
11104	Apo A1/B Standard	Others
11105	Lp(a)	Others
11105600	Lp(a)	Others
11107	Lp(a) Standard	Others
11110	Complement C3	Others
11110600	Complement C3	Others
11113	Complement C4	Others
11113600	Complement C4	Others
11115	Transferrin	Others
11115600	Transferrin	Others
11117	C3/C4/TRF Standard	Others
11120	Microalbumin	Others
11120600	Microalbumin	Others
11124	Microalbumin Standard	Others
11140	Homocysteine liquiUV	Others
11140600	Homocysteine liquiUV	Others
11141	CRP Buffer	Others
11143	Homocysteine liquiUV Control Set	Others
11145	Homocysteine liquiUV Calibrator Set	Others
11150	Cystatin-C liquidirect	Others
11150600	Cystatin-C liquidirect	Others
11153	Cystatin-C liquidirect Controls	Others
11155	Cystatin-C liquidirectCalibrators	Others
11241	CRP	Others
11241600	C-Reactive Protein (CRP)	Others
11251300	Anti-Streptolysin-O	Others
11251600	Anti-Streptolysin-O	Others
11251P	ASO Reagent Kit	Others
11261P	RF Reagent Kit	Others
11261300	Rheumatoid Factors	Others
11261600	Rheumatoid Factors	Others
11261PA	RF Reagent Kit	Others
11341	CRP Standard	Others
11351	ASO Standard	Others

Cat.-no.	Product name	Class
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
12024	LDH liquiUV	Others
12026	Lipase liquicolor	Others
12027	Alkaline Phosphatase liquicolor	Others

Cat.-no.	Product name	Class
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
157004	Total Protein liquicolor	Others
15650	HumaClot Duo ^{plus}	Others
15660	HumaClot Quattro	Others

Cat.-no.	Product name	Class
15800	HumaClot Pro	Others
15800/20	HumaClot Pro – Wash Solution	Others
15800/30	HumaClot Pro – Cleaner	Others
16001/03	Micro Cuvettes Hb	Others
16070	HumaMeter Hb ^{plus}	Others
16070/1	Reagent Hb	Others
16070/25		
16070/2	Calibrator Set Hb	Others
16070/3	Control Set Hb	Others
16080	HumaMeter A1c	Others
16085/50	HumaMeter A1c Reagent Kit	Others
16086	HumaMeter A1c Control Kit	Others
16180	HumaNex A1c	Others
16185	HumaNex A1c Reagent Kit	Others
16300	ELISYS QUATTRO	Others
16350/10	HC5-Basolyse	Others
16350/20	HC5-Eolyse	Others
16350/40	HC5-Control	Others
16420/30	HumaCount 30 ^{TS}	Others
16420/80	HumaCount 80 ^{TS}	Others
16430	HumaCount 5L	Others
16430/10	Automatic Sample Loader	Others
16430/20	HC5L-Diluent	Others
16430/30	HC5L-Lyse	Others
16430/40	HC5L-Diff	Others
16430/50	HC5L-Control	Others
16450	HumaCount 5D	Others
16450/10	HC5D Diluent	Others
16450/20	HC5D CBC Lyse	Others
16450/30	HC5D Diff Lyse	Others
16450/40	HC5D Control	Others
16450/60	HC5D Clean	Others
16670	Humareader HS	Others
16660	HumaStar 600	Others
16660/11	ISE Cleaner	Others
16660/12	ISE Conditioner	Others
16660/13	ISE Urine Diluent	Others
16660/14	ISE Standard Pack	Others
16661/01	Chimney	Others
16663/10	Diluent	Others
16663/11	Diluent-2	Others
16663/20	Cuvette Clean	Others
16663/25	Tip Cleaning Kit	Others
16700	Humalyzer 3000	Others
16800	Humalyzer 3500	Others
16880	HumaStar 80	Others
16890	HumaStar 100	Others
16895	HumaStar 200	Others
16930	HumaStar 300SR	Others
16923/20	Cuvette Clean	Others



Cat.-no.	Product name	Class
17200	ELISYS DUO	Others
17350	ELISYS UNO	Others
17400/10	HC-Diluent	Others
17400/11	HC-Diluent	Others
17400/20	HC-Lyse CF	Others
17400/22	HC-Lyse CF	Others
17400/30	HC-Cleaner	Others
17400/31	HC-Cleaner	Others
17400/40	HC-Control	Others
17400/50	HC-Calibrator	Others
17470/10	HumaLyte Plus ³	Others
17470/20	HumaLyte Plus ⁵	Others
17470/11	K Electrode	Others
17470/12	Na Electrode	Others
17470/13	Cl Electrode	Others
17470/14	Ca Electrode	Others
17470/15	pH Electrode	Others
17470/17	Reference Electrode	Others
17470/70	QC Solution	Others
17470/71	Daily Cleaning Solution	Others
17470/72	Weekly Cleaning Solution	Others
17470/74	K Filling Solution	Others
17470/75	pH / Na / Cl Filling Solution	Others
17470/76	Ca Filling Solution	Others
17470/78	Reference Filling Solution	Others
17470/79	Na Conditioner	Others
17470/82	Reagent Pack HumaLyte Plus ³	Others
17470/83	Reagent Pack HumaLyte Plus ⁵	Others
17470/86	Urine Diluent	Others
17470/110	QC Solution	Others
17546	HumaSens ^{plus} Uric Acid Test Strips	Others
17546/10	HumaSens ^{plus} Uric Acid Control Solution normal	Others
17547	HumaSens ^{plus} Total Cholesterol Test Strips	Others
17547/10	HumaSens ^{plus} Total Cholesterol Control Solution normal	Others
17560	HumaSens 2.0 Starter Pack	II,B
17561	HumaSens 2.0 ^{plus} Starter Pack	Others
17562	Glucose Test Strips Blue HumaSens2.0/ HumaSens2.0 ^{plus} / HumaSens/HumaSens ^{plus}	II,B
17562/2	Glucose Test Strips Blue HumaSens2.0/ HumaSens2.0 ^{plus} / HumaSens/HumaSens ^{plus}	II,B
17562/10	Glucose Control HumaSens* / HumaSens ^{plus} * / HumaSens 2.0 / HumaSens2.0 ^{plus} (*BLUE GLU strip)	II/B
17566	Uric Acid Test Strips HumaSens 2.0 ^{plus}	Others
17566/10	Uric Acid Control Solution HumaSens 2.0 ^{plus}	Others
17567	Total Cholesterol Test Strips HumaSens 2.0 ^{plus}	Others
17567/10	Total Cholesterol Control Solution HumaSens 2.0 ^{plus}	Others
17600	Combilyzer ¹³	Others

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

Cat.-no.	Product name	Class
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 95G	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, 31003	HemoStat Thromboplastin-SI	Others
31012	HemoStat Thromboplastin ^{liquid}	Others
32002	HemoStat Fibrinogen	Others
33002, 33012 33013 33022	HemoStat aPTT-EL	Others
34002	HemoStat Thrombin Time	Others
35001, 35002	HemoStat Control Plasma (normal, abnormal)	Others
35500	HemoStat Calibrator	Others
36002	HemoStat D-Dimer	Others
36012	HemoStat D-Dimer Control high/low	Others
36102	HemoStat Antithrombin liquid	Others
40030, 40031	SLE Latex Test	Others
40037	Glycin-NaCl buffer	Others
40038, 40039	I.M. Quick	Others
40042, 40043, 40040	Humatex CRP	Others
40052, 40053, 40050	Humatex RF	Others
40062, 40063, 40060	Humatex ASO	Others
50001, 50002, 50016	Syphilis RPR	Others
50101	Syphilis TPHA	Others
50201, 50200, 50211, 50221, 50231, 50241, 50251, 50261, 50271, 50281, 50291 50301	HUMATEX Febrile Antigens	Others

Cat.-no.	Product name	Class
51005	Syphilis Screen	Others
51015	IgE total ELISA	Others
51048	HBsAg ELISA	II, A
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
54025	ft4 ELISA	Others
54030	TSH ELISA	Others
55010	Testosterone ELISA	Others

Cat.-no.	Product name	Class
55020	Progesterone ELISA	Others
55030	Estradiol ELISA	Others
55040	Estriol ELISA	Others
55050	Cortisol ELISA	Others
55060	DHEA-S ELISA	Others
55500	25-OH Vitamin D	Others
57002P, 57004P	Hexagon HIV	II, A
57351	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 ^{Serum/Urine}	Others
68902, 68932	Hexagon hCG 1-Step ^{Serum/Urine}	Others
71012	HumaType Anti-A	II, A
71022	HumaType Anti-B	II, A
71032	HumaType Anti-A,B	II, A
71042	HumaType Anti-D IgM	II, A
71052	HumaType Anti-D IgM/IgG	II, A
71062	HumaType Anti-Human Globulin	II, B
71072	HumaType Albumin 22%	Others
73005/12	HumaTube No Additive (Z)	Others
73020/12	HumaTube Serum C/A (Z)	Others
73023/12	HumaTube Serum C/A (Z)	Others
73030/12	HumaTube Serum Gel-C/A (Z)	Others
73032/12	HumaTube K2-EDTA (K2E)	Others
73040/12	HumaTube K3-EDTA (K3E)	Others
73045/12	HumaTube K3-EDTA (K3E)	Others
73050/12	HumaTube Li-Heparin (LH)	Others
73060/12	HumaTube Na-Citrate 3.2 % (9NC)	Others
73070/12	HumaTube Glucose (FH)	Others
961000	HumaLoop T	Others
962000	HumaLoop M	Others
963100	HumaTurb A	Others
963200	HumaTurb C + A	Others
964000	HumaHeat	Others
ITC02850	HumaScan	Others
ITC30500	IMTEC-Gliadin-Antibodies IgG	Others
ITC30505	IMTEC-d-Gliadin-Antibodies IgG	Others
ITC30600	IMTEC-Gliadin-Antibodies IgA	Others
ITC30605	IMTEC-d-Gliadin-Antibodies IgA	Others
ITC30701	IMTEC-Gastro-LIA	Others
ITC40040	IMTEC-Salmononella-Antibodies Screen (cut-off)	Others
ITC40050	IMTEC-Salmononella-Antibodies IgA (cut-off)	Others

Cat.-no.	Product name	Class
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
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

Cat.-no.	Product name	Class
ITC70024	IMTEC-SS-B/La-Antibodies	Others
ITC70025	IMTEC-Jo1-Antibodies	Others
ITC70026	IMTEC-SS-A/Ro-Antibodies	Others
ITC70028	IMTEC-Scl70-Antibodies	Others
ITC80000	HumaBlot 44 ^{FA}	Others
ITC82020	IMTEC-PR3-ANCA	Others
ITC82030	IMTEC-MPO-ANCA	Others
ITC82040	IMTEC-Vasculitis-LIA	Others
ITC82070	IMTEC-GBM-Antibodies	Others
ITC85010	IMTEC-TG-Antibodies	Others

Cat.-no.	Product name	Class
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 Council Directive:

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)

Authorised representative:

Name: SYSMEX EUROPE GMBH

Address: Bornbarch 1, 22848 Norderstedt, Germany

Authorised officer: Kohei Sumitani
Kohei Sumitani, Managing Director

Date: 31.1.2014

Legal Manufacturer:

Name: SYSMEX CORPORATION

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

Authorised officer: Keiji Fujimoto
Keiji Fujimoto, Executive Officer

Date: Jan. 23, 2014





SYSMEX CORPORATION

Mail to : 1-5-1 Wakino-hama-Kaigandori, Chuo-ku, Kobe 651-0073, Japan
Phone : 81-78-265-0500
Facsimile : 81-78-265-0524

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 product is in conformity with Directive **98/79/EC** based on the test results using harmonised standards in accordance with Article 5 of the Directive.

Product identification:

Product: REACTION TUBE

Model: SU-40

Manufacturer:

Name: SYSMEX CORPORATION

Address: 1-5-1 Wakino-hama-Kaigandori, Chuo-ku, Kobe 651-0073

Country: Japan

Authorised representative:

Name: SYSMEX EUROPE GMBH

Address: Bornbarch 1, 22848 Norderstedt

Country: Germany

Authorised officer:


Iwane Matsui

Position: President

Date: 10TH JANUARY 2002

Place: NORDERSTEDT, GERMANY

This certificate was issued under sole responsibility of:

Authorised officer:


Tokuhiro Okada

Position: Vice President, Technology Control

Date: November 16, 2001

Place: Japan

