



<b>PRODUCT NAME</b>	<b>CODE</b>
<b>CLINICAL CHEMISTRY - BIOCHEMISTRY</b>	
<b>a-AMYLASE - DIRECT</b>	11583
	11550
	12550
	21550
	23550
<b>a-AMYLASE - EPS</b>	11534
	21534
<b>a-AMYLASE-PANCREATIC</b>	11799
	12799
	21799
<b>ACID PHOSPHATASE (ACP)</b>	11548
<b>ALANINE AMINOTRANSFERASE (ALT/GPT)</b>	11832
	11533
	11568
	11562
	12533
	21533
	23533
<b>ALBUMIN</b>	11573
	11547
	12547
	21547
	23547
<b>ALKALINE PHOSPHATASE (ALP) - AMP</b>	11592
	11593
	11598
	12518
	21592
	23592
<b>ALKALINE PHOSPHATASE (ALP) - DEA</b>	11590
	11591
	11597
	12514
	21590
	23590
<b>ASPARTATE AMINOTRANSFERASE (AST/GOT)</b>	11830
	11531
	11567
	11561
	12531
	21531
	23531
<b>BILIRUBIN (DIRECT)</b>	11511
	11545
	21504

PRODUCT NAME	CODE
	23504
BILIRUBIN (TOTAL AND DIRECT)	11515
	11555
BILIRUBIN (TOTAL)	11510
	11544
	21506
	23506
CALCIUM-ARSENAZO	11570
	11571
	12570
	21570
	23570
CALCIUM-CRESOLPHTHALEIN	11811
	11812
	12513
	21511
	23511
CALCIUM-MTB	11527
	11507
CARBON DIOXIDE (CO2)	11558
	11827
	12558
	21558
CHOLESTEROL	11805
	11505
	11506
	11539
	12505
	21505
	23505
	11523
CHOLESTEROL HDL DIRECT	11557
	12557
	21557
	23557
CHOLESTEROL HDL PRECIPITATING REAGENT	11648
CHOLESTEROL LDL DIRECT	11585
	12585
	21585
	23585
CHOLESTEROL LDL PRECIPITATING REAGENT	11579
CHOLINESTERASE (CHE)	11588
	11589
	21588
CITRATE	11795
	11895
	23795
CREATINE KINASE (CK)	11790
	11791
	12524
	21790

P. 2.1.

PRODUCT NAME	CODE
	23790
CREATINE KINASE-MB (CK-MB)	11792
	12566
	21792
	23792
CREATININE	11802
	11502
	11542
	12502
	21502
	23502
CREATININE-ENZYMATIC	11734
	12734
	21734
FRUCTOSAMINE	11046
FRUCTOSE	11794
	23794
g-GLUTAMYLTRANSFERASE (g-GT)	11584
	11520
	12520
	21520
	23520
GLUCOSE	11803
	11503
	11504
	11538
	12503
	21503
	23503
GLUCOSE-HEXOKINASE	11656
	12756
	21656
	23656
IRON- CHROMAZUROL	11546
IRON-FERROZINE	11509
	12509
	21509
	23509
LACTATE	11736
	12736
	21736
	23736
LACTATE DEHYDROGENASE (LDH)	11580
	11581
	12580
	21580
	23580
LACTATE DEHYDROGENASE (LDH) - IFCC	11586
	11587
	21586
	23586

P-21

<b>PRODUCT NAME</b>	<b>CODE</b>
<b>LIPASE</b>	11793
	12793
	23793
<b>MAGNESIUM</b>	11797
	12797
	21797
	23797
<b>PHOSPHORUS</b>	11508
	12508
	21518
	23518
<b>PROTEIN (TOTAL)</b>	11800
	11572
	11500
	11553
	12500
	21513
	23513
<b>PROTEIN (URINE)</b>	11501
	11559
	12501
	21512
	23512
<b>PYRIDOXAL PHOSPHATE</b>	11666
<b>TOTAL IRON BINDING CAPACITY (TIBC)</b>	11554
<b>TRIGLYCERIDES</b>	11828
	11528
	11529
	12528
	21528
	23528
<b>UNSATURATED IRON BINDING CAPACITY (UIBC)</b>	11835
	12835
	21835
<b>UREA/BUN - COLOR</b>	11536
	11537
<b>UREA/BUN - UV</b>	11516
	11517
	11541
	12516
	21516
<b>URIC ACID</b>	23516
	11821
	11521
	11522
	11540
	12521
21521	
23521	
<b>ZINC</b>	12526
<b>CLINICAL CHEMISTRY - TURBIDIMETRY</b>	

175

<b>PRODUCT NAME</b>	<b>CODE</b>
a1-ACID GLYCOPROTEIN	31928
	23107
ALBUMIN (MICROALBUMINURIA)	31324
	31924
	13324
	22324
	23324
ACTIVATED PARTIAL THROMBOPLASTIN TIME (APTT)	61004
	61005
	61009
ANTI-STREPTOLYSIN O (ASO)	31323
	31923
	31031
	13923
	22923
	23923
ANTITHROMBIN III	31936
	13936
	22936
	23936
APOLIPOPROTEIN A-I (APO A-I)	31095
	23095
APOLIPOPROTEIN B (APO B)	31098
	23098
b2-MICROGLOBULIN	31925
	22925
	23925
COMPLEMENT COMPONENT C3	31073
	31079
	13084
	23103
COMPLEMENT COMPONENT C4	31074
	31080
	13085
	23104
C-REACTIVE PROTEIN (CRP)	31321
	31921
	31029
	13921
	22921
	23921
C-REACTIVE PROTEIN-hs (CRP-hs)	31927
	13927
	22927
	23927
FERRITIN	31934
	31935
	22934
	23934
	13934

2-4-1

<b>PRODUCT NAME</b>	<b>CODE</b>
<b>FIBRINOGEN</b>	31600
	13600
	22804
	23804
<b>FIBRINOGEN CLAUSS</b>	61002
	61003
	61020
<b>HEMOGLOBIN A1C-DIRECT (HbA1C-DIR)</b>	31047
	13047
	22047
	22147
<b>IMMUNOGLOBULIN A (IgA)</b>	31071
	31077
	13082
	23101
<b>IMMUNOGLOBULIN G (IgG)</b>	31070
	31076
	13081
	23100
<b>IMMUNOGLOBULIN M (IgM)</b>	31072
	31078
	13083
	23102
<b>PREALBUMIN</b>	31929
	23106
<b>PROTHROMBIN TIME (PT)</b>	61001
<b>RHEUMATOID FACTORS (RF)</b>	31322
	31922
	31030
	13922
	22922
23922	
<b>THROMBIN TIME (TT)</b>	61000
<b>TRANSFERRIN</b>	31091
	31092
	31093
	13091
	22105
	23105
<b>CLINICAL CHEMISTRY - MICROCOLUMN CHROMATOGRAPHY</b>	
<b>17-HYDROXYCORTICOSTEROIDS (17-OH)</b>	11006
<b>17-KETOSTEROIDS</b>	11002
<b>5-AMINOLEVULINIC ACID (ALA) / PORPHOBILINOGEN (PBG)</b>	11017
<b>5-HYDROXYINDOLEACETIC ACID (5-HIAA)</b>	11010
<b>HEMOGLOBIN A2</b>	11077
<b>METANEPHRINES</b>	11022
<b>VANILMANDELIC ACID</b>	11003
<b>CLINICAL CHEMISTRY - STANDARDS &amp; CALIBRATORS</b>	

P-511

<b>PRODUCT NAME</b>	<b>CODE</b>
ADENOSINE DEAMINASE (ADA) STANDARD	18052
ALBUMIN (MICROALBUMINURIA) STANDARD	18011
AMMONIA/ETHANOL/CO2 CALIBRATOR	18065
ANTI-STREPTOLYSIN O (ASO) STANDARD	31119
APOLIPOPROTEIN A-I (APO A-I) STANDARD	31100
APOLIPOPROTEIN B (APO B) STANDARD	31200
b2-MICROGLOBULIN STANDARD	31122
BILIRUBIN STANDARD	11693
BIOCHEMISTRY CALIBRATOR	31075
BIOCHEMISTRY CALIBRATOR (HUMAN)	18044
CARBON DIOXIDE STANDARD	11822
	11833
CHOLESTEROL HDL/LDL CALIBRATOR	11824
COAGULATION CALIBRATOR	61006
CREATINE KINASE-MB (CK-MB) STANDARD	11750
CRP/CRP-hs STANDARD	31113
CRP-er STANDARD	31182
FERRITIN STANDARD	31127
FIBRINOGEN STANDARD	31601
HEMOGLOBIN A1C-DIRECT (HbA1C-DIR) STANDARDS	31048
HOMOCYSTEINE STANDARDS	11603
PREALBUMIN STANDARD	31196
PROTEIN (URINE) STANDARD	31130
PROTEIN CALIBRATORS	11513
RHEUMATOID FACTORS (RF) STANDARD	31116
<b>CLINICAL CHEMISTRY - INSTRUMENTS</b>	
A15	83105
A25	83101
BA400	83400
BA200	83200
BTS-350	80175
<b>CONSUMABLES (INSTRUMENTS)</b>	
ALKALINE WASHING SOLUTION	AC17204
	AC17205
ACID WASHING SOLUTION	AC17200
	AC17201
CONCENTRATED SYSTEM LIQUID	BO11524
CONCENTRATED SYSTEM LIQUID 2	AC17206
CONCENTRATED WASHING SOLUTION	BO13416
	AC16434
Reaction Rotor	AC11485
Sample Wells (1000 units)	AC10770
WASHING SOLUTION	AC10415
	BO10771
<b>CLINICAL CHEMISTRY - BIOCHEMISTRY - REAGENTS AUTOMATED SYSTEMS A15/A25</b>	
ADENOSINE DEAMINASE (ADA)	12754
	23754
AMMONIA	12532
	23532

25/11

PRODUCT NAME	CODE
ANGIOTENSIN CONVERTING ENZYME (ACE)	12796
	21796
b-HYDROXYBUTYRATE	12525
	21525
ETHANOL	12789
	21789
HOMOCYSTEINE	12737
	21737
	23737
OXALATE	12539
OXALATE PRETREATMENT REAGENTS	11839
TOTAL BILE ACIDS	12551
	21551
	23551
a-1-Microglobulin	22941
C-REACTIVE PROTEIN-er (CRP-er)	22942
	23942
<b>CLINICAL CHEMISTRY - INTERNAL QUALITY CONTROL</b>	
ADA CONTROLS	18048
AMMONIA/ETHANOL/CO2 CONTROL I	18063
AMMONIA/ETHANOL/CO2 CONTROL II	18064
b2-MICROGLOBULIN CONTROL URINE	31215
b2-MICROGLOBULIN CONTROLS	31592
BIOCHEMISTRY CONTROL SERUM (HUMAN) I	18042
BIOCHEMISTRY CONTROL SERUM (HUMAN) II	18043
BIOCHEMISTRY CONTROL SERUM I	18009
	18005
BIOCHEMISTRY CONTROL SERUM II	18010
	18007
BIOCHEMISTRY CONTROL URINE	18054
BIOCHEMISTRY CONTROL URINE II	18066
CK-MB CONTROL SERUM	18024
CK-MB CONTROL SERUM II	18061
COAGULATION CONTROL I	61007
COAGULATION CONTROL II	61008
CONTROL URINE	18036
	18037
FERTILITY BIOCHEMISTRY CONTROL	18053
FIBRINOGEN CONTROL PLASMA	31602
FRUCTOSAMINE CONTROL SERUM	18057
HEMOGLOBIN A1C CONTROL (ELEVATED)	18002
HEMOGLOBIN A1C CONTROL (NORMAL)	18001
HEMOGLOBIN A2 CONTROL	10011
HOMOCYSTEINE CONTROL I	18058
HOMOCYSTEINE CONTROL II	18059
LIPID CONTROL SERUM I	18040
LIPID CONTROL SERUM II	18041
OXALATE CONTROL URINE	18062
PROTEIN CONTROL SERUM I	31211
PROTEIN CONTROL SERUM II	31212

17-51

<b>PRODUCT NAME</b>	<b>CODE</b>
RHEUMATOID CONTROL SERUM I	31213
RHEUMATOID CONTROL SERUM	31214
<b>AUTOIMMUNITY - IFA (IMMUNOFLUORESCENCE)</b>	
ANTI-ADRENAL CORTEX ANTIBODIES (AACA)	44574
	44575
	29022
ANTI-ENDOMYSIUM ANTIBODIES (AEA)	44148
	44548
	44715
	44557
	44710
ANTI-ISLET CELL ANTIBODIES (AICA)	44609
	44572
ANTI-KERATIN ANTIBODIES (AKA)	44618
	44517
ANTI-MITOCHONDRIAL ANTIBODIES (AMA)	44510
	44514
	44511
	44515
ANTI-nDNA ANTIBODIES (nDNA)	44825
	44818
	44817
	44820
	44819
ANTI-NEUTROPHIL CYTOPLASMIC ANTIBODIES (ANCA)	44850
	44851
	44852
	44911
ANTI-NUCLEAR ANTIBODIES HEp-2 (ANA-HEp-2)	44108
	44508
	44509
	44546
	44547
ANTI-NUCLEAR ANTIBODIES RL (ANA-RL)	44506
	44507
ANTI-SKIN ANTIBODIES (ASA)	44560
	44561
ANTI-SMOOTH MUSCLE ANTIBODIES (ASMA)	44520
	44524
	44521
	44525
ANTI-STRIATED MUSCLE ANTIBODIES (AStMA)	44649
	29017
ANTI-THYROID ANTIBODIES (ATA)	44550
	44551
	29012
AUTOANTIBODIES DUO-HEp2/ML (DUO-HEp2/ML)	44874
AUTOANTIBODIES MSK/MSS (AA-MSK/MSS)	44518
AUTOANTIBODIES MSL/MSK/MSS (AA-MSL/MSK/MSS)	44826
	44827

P-51

<b>PRODUCT NAME</b>	<b>CODE</b>
AUTOANTIBODIES-RK/RS (AA-RK/RS)	44758
	44568
AUTOANTIBODIES-RL/RK/RS (AA-RL/RK/RS)	44558
	44648
	44570
	44639
GLOMERULAR BASEMENT MEMBRANE ANTIBODIES (GBMA)	44588
<b>AUTOIMMUNITY - IFA (IMMUNOFLUORESCENCE) - AUXILIARY REAGENTS</b>	
AACA POSITIVE CONTROL	44578
AEA POSITIVE CONTROL	44549
	44893
	44732
AICA POSITIVE CONTROL	44577
AKA POSITIVE CONTROL	44619
AMA POSITIVE CONTROL	44512
	44891
ANA-Ce POSITIVE CONTROL	44585
ANA-Ho POSITIVE CONTROL	44502
	44890
ANA-Nu POSITIVE CONTROL	44504
ANA-Sp POSITIVE CONTROL	44503
APCA POSITIVE CONTROL	44532
ASA-bm POSITIVE CONTROL	44562
ASA-is POSITIVE CONTROL	44563
ASMA POSITIVE CONTROL	44522
	44892
AStMA POSITIVE CONTROL	44883
ATA POSITIVE CONTROL	44553
BLOTTING PAPER 12	44669
BLOTTING PAPER 4	44731
BLOTTING PAPER 6	44667
BLOTTING PAPER 8	44716
C-ANCA POSITIVE CONTROL	44854
	44912
FITC/EVANS (R)	44590
	44836
	44916
GBMA POSITIVE CONTROL	44678
GLYCIN	44846
IgA FITC/EVANS	44692
	44835
IgG FITC/EVANS	44697
	44834
IgG FITC/EVANS (M)	44847
	44882
LKM POSITIVE CONTROL	44766
MOUNTING MEDIUM	44694
nDNA POSITIVE CONTROL	44542
	44894

2-4-1

<b>PRODUCT NAME</b>	<b>CODE</b>
NEGATIVE CONTROL	44696
	44889
P-ANCA POSITIVE CONTROL	44855
	44913
PBS (10x)	44592
X-ANCA POSITIVE CONTROL	44896
<b>AUTOIMMUNITY - ELISA</b>	
ANA-SCREENING	44785
ANTI-ANNEXIN V IgG/IgM (ANX)	44869
ANTI-beta-2-GLYCOPROTEIN 1 IgG/IgM (beta2GP1)	44868
ANTI-BPI ANTIBODIES	44905
ANTI-CARDIOLIPIN ANTIBODIES (ACA-IgG/IgM)	44780
ANTI-CATHEPSIN G ANTIBODIES	44906
ANTI-CENTROMERE B ANTIBODIES (CENP-B)	44865
ANTI-CITRULLINATED PROTEIN ANTIBODIES (ACPA)	44860
ANTI-DEAMIDATED GLIADIN PEPTIDES IgA (DGP IgA)	44885
ANTI-DEAMIDATED GLIADIN PEPTIDES IgG (DGP IgG)	44884
ANTI-dsDNA ANTIBODIES	44705
ANTI-ELASTASE ANTIBODIES	44907
ANTI-GBM ANTIBODIES-EIA (GBM)	44870
ANTI-GLIADIN ANTIBODIES (AGA-IgG/IgA)	44704
ANTI-HISTONES ANTIBODIES (HIS)	44862
ANTI-INSULIN ANTIBODIES (INS)	44873
ANTI-Jo1 ANTIBODIES	44864
ANTI-LACTOFERRIN ANTIBODIES	44908
ANTI-LYSOZYME ANTIBODIES	44909
ANTI-M2 ANTIBODIES (M2)	44871
ANTI-MPO ANTIBODIES (P-ANCA)	44790
ANTI-NUCLEOSOME ANTIBODIES (NCL)	44861
ANTI-PHOSPHOLIPID IgG/IgM (APLA)	44867
ANTI-PR3 ANTIBODIES (C-ANCA)	44791
ANTI-RIBOSOMAL P ANTIBODIES (Rib P)	44866
ANTI-Sci70 ANTIBODIES	44863
ANTI-Sm ANTIBODIES	44755
ANTI-Sm/RNP ANTIBODIES	44770
ANTI-SSA (Ro) ANTIBODIES	44765
ANTI-SS-B (La) ANTIBODIES	44750
ANTI-THYROGLOBULIN ANTIBODIES (ANTI-Tg)	44796
ANTI-THYROID PEROXIDASE ANTIBODIES (ANTI-TPO)	44795
ANTI-tTRANSGLUTAMINASE ANTIBODIES IgA (ANTI-tTG IgA)	44754
ANTI-tTRANSGLUTAMINASE ANTIBODIES IgG (ANTI-tTG IgG)	44798
ASCA-IgG/IgA (ASCA)	44872
ENA 4-PROFILE	44775
ENA 6-PROFILE	44910
ENA 6-SCREENING	44740
<b>AUTOIMMUNITY - INSTRUMENTS</b>	

2-21

<b>PRODUCT NAME</b>	<b>CODE</b>
iPRO	84101
<b>RAPID TESTS - LATEX AGGLUTINATION</b>	
<b>ANTI-STREPTOLYSIN O (ASO) - SLIDE</b>	31019
	31319
	31086
	31448
<b>C-REACTIVE PROTEIN (CRP) - SLIDE</b>	31011
	31311
	31012
	31107
<b>RHEUMATOID FACTORS (RF) - SLIDE</b>	31013
	31313
	31014
	31108
<b>INFECTIOUS IMMUNOLOGY - SYPHILIS</b>	
<b>RPR-CARBON</b>	36001
	36002
<b>TPHA</b>	36005
<b>INFECTIOUS IMMUNOLOGY - FEBRILE ANTIGENS</b>	
<b>BRUCELLA ABORTUS</b>	33309
<b>BRUCELLA ABORTUS, ROSE BENGAL</b>	33315
<b>BRUCELLA POSITIVE CONTROL</b>	33509
<b>FEBRILE SERODIAGNOSTICS MULTISCREENING</b>	33001
<b>FEBRILE SERODIAGNOSTICS SALMONELLA</b>	33080
	33081
<b>PROTEUS OX19</b>	33311
<b>PROTEUS POSITIVE CONTROL</b>	33502
<b>SALMONELLA PARATYPHI AH</b>	33301
<b>SALMONELLA PARATYPHI AO</b>	33302
<b>SALMONELLA PARATYPHI BH</b>	33303
<b>SALMONELLA PARATYPHI BO</b>	33304
<b>SALMONELLA PARATYPHI CH</b>	33305
<b>SALMONELLA PARATYPHI CO</b>	33306
<b>SALMONELLA POSITIVE CONTROL</b>	33510

P-6.1.



## Declaration of Conformity

**Manufacturer:** Beijing Mindray Medical Instrument Co., Ltd.  
1F,2F,4F&5F, Building 3, No. 18 Science Park Road,  
Life Science Park, Changping District, Beijing 102206,  
China

**Manufacturer SRN:** CN-MF-000022542

**Authorized Representative:** Shanghai International Holding Corp. GmbH (Europe)  
Eiffestraße 80 20537 Hamburg, Germany

**Product:** **Auto Coagulation Analyzer**

**Modle:** **C3100**

**Basic UDI-DI:** **697080106A0320F05ETH**

**Classification:** Class A (According to Rule 5 of IVDR annex VIII)

**Conformity Assessment Route:** Annex II and III of IVDR

**GMDN code:** 56689

**We declare that the above mentioned products meet the provisions of the REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT and OF THE COUNCIL. All supporting documentations are retained under the premises of the manufacturer. This declaration of conformity is issued under the sole responsibility of the manufacturer.**

**References to CS:** /

**Notified Body:** /

**Notified Body No. :** /

**Identification of the Certificate:** /

**Start of CE-Marking:** **2022-02-15**

I hereby am appointed as the authorized person to deal with all the registration and quality management affairs in my capacity as Management Representative of Beijing Mindray Medical Instrument Co., Ltd., Effective immediately.

**Place, Date of Issue:** Beijing,

**Signature:**

**Name of Authorized Signatory:** Mr. Ge Pengfei

**Position Held in Company:** Management Representative

**Declaration of Conformity V 1.0**

**Applied Standards List**

**Product:** Auto Coagulation Analyzer

**Catalogue Number:** C3100

**Standards Applied:**

EN ISO 18113-1:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements (ISO 18113-1:2009)
EN ISO 18113-3:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 3: In vitro diagnostic instruments for professional use (ISO 18113-3:2009)
EN ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
EN ISO 14971:2019	Medical devices - Application of risk management to medical devices (ISO 14971:2019)
EN 13612:2002/AC:2002	Performance evaluation of in vitro diagnostic medical devices
EN 62304:2006/A1:2015	Medical device software - Software life-cycle processes
EN 61010-1:2010/A1:2019	Safety requirements for electrical equipment for measurement, control, and laboratory use Part 1: General requirement
EN IEC 61010-2-081:2020	Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes
IEC 61010-2-101:2018	Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment
EN 61010-2-010:2020	Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-010: Particular requirements for laboratory equipment for the heating of materials

**Declaration of Conformity V 1.0**

EN 62366-1:2015	Medical devices - Part 1: Application of usability engineering to medical devices
EN 61326-1:2013	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements
EN 61326-2-6:2013	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment