

“Echipamed-Plus” SRL
str. Valea Trandafirilor, 24B, of. 2-7
MD-2001, Chisinau, Moldova
+373 22 234-349

Date: 07.02.2025

LETTER OF AUTHORIZATION

To whom it may concern,

We, Shenzhen Mindray Bio-Medical Electronics Co., Ltd., (“Mindray”) manufacturer of biochemical, immunological and coagulation analyzers, reagents and consumables (“Product(s)”), hereby certify that “Echipamed-Plus” SRL, with business office at str. Valea Trandafirilor, 24B, of. 2-7, MD-2001, Chisinau, Republic of Moldova (“You”) is our official distributor and local representative for registration, sales and service of the Product(s) in Republic of Moldova (“Territory”).

As the manufacturer, Mindray guarantees the Product(s) against defects in materials and workmanship, and provide services based on the standard terms and conditions of Mindray’s warranty policy.

This authorization of distribution rights is valid from the date of issuance to **December 31, 2025**. Mindray reserves the right to terminate the authorization upon fifteen (15) days written notice without any compensation to You.

Neither this Letter of Authorization nor any further extension, will impose any obligation or grant any rights regarding further distribution of the Product(s), nor allow any party to seek compensation for goodwill developed during the term of Letter of Authorization or any further extension.

Best regards,




Gao Xiufu
Regional Sales & Marketing Manager, IVD Sales & Marketing Department, Central Asia
Shenzhen Mindray Bio-Medical Electronics Co., Ltd.

SHENZHEN MINDRAY
BIO-MEDICAL ELECTRONICS CO., LTD.
Mindray Building, Keji 12th Road South,
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TÜV SÜD
 ZERTIFIKAT ♦ CERTIFICATE ♦ 認證證書 ♦ СЕРТИФИКАТ ♦ CERTIFICADO ♦ CERTIFICAT



CERTIFICATE

No. QS5 044751 0140 Rev. 05

Overall Scope Statement:

Design and Development, Production and Distribution of Equipment (including Patient Monitor and Accessories, Vital Signs Monitor, Center Monitoring System, Telemetry Monitoring System, Pulse Oximeter, Temperature Probe, Flow Sensor, Ambulatory Blood Pressure Monitor, Defibrillator / Monitor and Accessories, Electrocardiograph, Anesthesia Machine and Accessories, Ventilator, Air Compressor, Endoscope Camera System, Endoscope Light Source and Accessories, Ultrasonic Diagnostic Equipment and Accessories, Digital Radiography System, Radiography System, Hematology Analyzer, Clinical Chemistry Analyzer, Urine Analyzer, Microplate Reader, Microplate Washer for In-Vitro Diagnostic Use, Chemiluminescence Immunoassay Analyzer, Flow Cytometer, (Auto) Sample Processing System, Auto Slide Maker and Stainer, Glycohemoglobin Analyzer, Specific Protein Analyzer), Reagents for Hematology Analyzer, Reagents for Clinical Chemistry Analyzer, Chemiluminescence Immunoassay Reagents, Chemiluminescence Immunoassay Calibrators and Controls, Reagents for Flow Cytometer, Reagents for Glycohemoglobin Analyzer, Calibrators and Controls for Glycohemoglobin Analyzer, Coagulation Analyzer and Accessories, Coagulation Reagents, Calibrators and Controls for Coagulation Analyzer, Automated Digital Cell Morphology Analyzer, Ion-Selective Electrodes, Disposable Anesthesia Mask, Reusable Anesthesia Mask, Respiratory Mask, Disposable Breathing Circuit, Reusable Breathing Circuit, Heat and Moisture Exchanger, Filter, Breathing Bag, Tympanic Thermometer, Wireless Module, Wireless Device

Page 2 of 4
Date of Issue: 2023-05-25

(Renee Walker)
Director, US Certification Body, MHS





Product Service

Certificate

No. Q5 044751 0164 Rev. 05

Holder of Certificate: **Shenzhen Mindray Bio-Medical Electronics Co., Ltd.**

Mindray Building
 Keji 12th Road South
 High-Tech Industrial Park
 Nanshan
 518057 Shenzhen
 PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate: **Design and Development, Production and Distribution of: Active Medical Devices(intended) for monitoring, diagnosis, anesthesia, breathing and intensive care; In-vitro Diagnostic Instruments; Non-active accessories for breathing therapy and anesthesia; In-vitro diagnostic reagents and kits(intended) for hematology, clinical chemistry, immunology and cell analysis (For detail information see following pages)**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 044751 0164 Rev. 05

Report No.: SH2305501

Valid from: 2023-09-01
Valid until: 2026-08-31

Date, 2023-06-19

C. Dicks

Christoph Dicks
 Head of Certification/Notified Body





Product Service

Certificate

No. Q5 044751 0164 Rev. 05

Applied Standard(s): EN ISO 13485:2016
 Medical devices - Quality management systems -
 Requirements for regulatory purposes
 (ISO 13485:2016)
 DIN EN ISO 13485:2016

Facility(ies): **Shenzhen Mindray Bio-Medical Electronics Co., Ltd.**
 Mindray Building, Keji 12th Road South, High-Tech Industrial Park,
 Nanshan, 518057 Shenzhen, PEOPLE'S REPUBLIC OF CHINA

Design and Development, Production and Distribution of: Active
 Medical Devices(intended) for monitoring, diagnosis, anesthesia,
 breathing and intensive care; In-vitro Diagnostic Instruments;
 Non-active accessories for breathing therapy and anesthesia; In-
 vitro diagnostic reagents and kits(intended) for hematology, clinical
 chemistry, immunology and cell analysis (For detail information
 see following pages)

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
 1203 Nanhuan Avenue, Guangming District, 518106 Shenzhen,
 PEOPLE'S REPUBLIC OF CHINA

Design and Development, Production and Distribution of: Active
 Medical Devices(intended) for monitoring, diagnosis, anesthesia,
 breathing and intensive care; In-vitro Diagnostic Instruments;
 Non-active accessories for breathing therapy and anesthesia; In-
 vitro diagnostic reagents and kits(intended) for hematology, clinical
 chemistry, immunology and cell analysis (For detail information
 see following pages)



ZERTIFIKAT ◆ CERTIFICATE ◆ 認 證 證 書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT



Certificate

No. Q5 044751 0164 Rev. 05

For the product(s)/product category (ies):

Patient Monitor and Accessories, Vital Signs Monitor, Center Monitoring System, Telemetry Monitoring System, Pulse Oximeter, Temperature Probe, Flow Sensor, Ambulatory Blood pressure Monitor , Defibrillator/Monitor and Accessories, Electrocardiograph, Anesthesia Machine and accessories, Ventilator, Air compressor, Endoscope Camera System, Endoscope Light Source and accessories, Ultrasonic Diagnostic Equipment and Accessories, Digital Radiography System, Radiography System, Hematology Analyzer, Clinical Chemistry Analyzer, Urine Analyzer, Microplate Reader, Microplate Washer for invitro diagnostic use, Chemiluminescence Immunoassay Analyzer, Flow Cytometer, (Auto) Sample Processing System, Auto Slide Maker&Stainer, Glycohemoglobin Analyzer, Specific Protein Analyzer, Reagents for Hematology Analyzer, Reagents for Clinical Chemistry Analyzer, Chemiluminescence Immunoassay Reagents, Chemiluminescence Immunoassay Calibrators and Controls, Reagents for Flow Cytometer, Reagents for Glycohemoglobin Analyzer, Calibrators and Controls for Glycohemoglobin Analyzer, Coagulation Analyzer and Accessories, Coagulation Reagents, Calibrators and Controls for Coagulation Analyzer, Automated Digital Cell Morphology Analyzer , Ion-Selective Electrodes, Disposable Anesthesia Mask, Reusable Anesthesia Mask, Respiratory Mask, Disposable Breathing Circuit, Reusable Breathing Circuit, Heat and Moisture Exchanger, Filter, Breathing Bag, Tympanic Thermometer.



Declaration of Conformity



Manufacturer: Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Mindray Building, Keji 12th Road South, High-Tech
Industrial Park, Nanshan, 518057, Shenzhen, P. R. China

Manufacturer SRN: CN-MF-000014156

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

Product: See Attachment I

Catalogue Number: See Attachment I

Classification: See Attachment I

Conformity Assessment Route: Annex IX excluding CHAPTER II

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: TÜV SÜD Product Service GmbH Ridlerstraße 65
80339 München, Germany.

Notified Body No. : 0123

Identification of the Certificate: NO. V12 044751 0190

Start of CE-Marking: 2022.8.25

I hereby am appointed as the authorized person to deal with all the registration and quality management affairs in my capacity as Manager of Technical Regulation Department of Shenzhen Mindray Bio-Medical Electronics Co., Ltd, Effective immediately.

Place, Date of Issue: Shenzhen, 2024.9.14

Signature:

Name of Authorized Signatory: Bobby Liu

Position Held in Company: Manager, Technical Regulation Department

Attachment I

CLIA reagents and consumables

| NO. | Product Name | Catalogue Number | Classification |
|------------|---|--------------------------------|--|
| 1 | Free Triiodothyronine (CLIA) | 105-004208-00 105-004235-00 | Class B (According to Rule 6 of IVDR Annex VIII) |
| 2 | Free Thyroxine (CLIA) | 105-004209-00 105-004236-00 | Class B (According to Rule 6 of IVDR Annex VIII) |
| 3 | Total Triiodothyronine (CLIA) | 105-004210-00 105-004237-00 | Class B (According to Rule 6 of IVDR Annex VIII) |
| 4 | Total Thyroxine (CLIA) | 105-004211-00 105-004238-00 | Class B (According to Rule 6 of IVDR Annex VIII) |
| 5 | Thyroid-Stimulating Hormone (CLIA) | 105-004212-00 105-004239-00 | Class B (According to Rule 6 of IVDR Annex VIII) |
| 6 | Antibody to thyroglobulin(CLIA) | 105-005664-00 105-005681-00 | Class B (According to Rule 6 of IVDR Annex VIII) |
| 7 | Antibody to thyroid peroxidase(CLIA) | 105-005665-00 105-005682-00 | Class B (According to Rule 6 of IVDR Annex VIII) |
| 8 | Thyroglobulin(CLIA) | 105-005663-00 105-005680-00 | Class B (According to Rule 6 of IVDR Annex VIII) |
| 9 | Reverse Triiodothyronine (CLIA) | 105-010692-00 105-010719-00 | Class B (According to Rule 6 of IVDR Annex VIII) |
| 10 | Anti-Thyrotropin Receptor Antibody (CLIA) | 105-010975-00 105-010976-00 | Class B (According to Rule 6 of IVDR Annex VIII) |
| 11 | Total β Human Chorionic Gonadotrophin II (CLIA) | 105-017089-00 105-017090-00 | Class B (According to Rule 6 of IVDR Annex VIII) |
| 12 | Follicle Stimulating Hormone (CLIA) | 105-004222-00 105-004249-00 | Class B (According to Rule 6 of IVDR Annex VIII) |
| 13 | Luteinizing Hormone (CLIA) | 105-004223-00 105-004250-00 | Class B (According to Rule 6 of IVDR Annex VIII) |

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| 14 | Prolactin (CLIA) | 105-004224-00 | Class C (According to Rule 3 of IVDR Annex VIII) |
| | | 105-004251-00 | |
| 15 | Estradiol (CLIA) | 105-004225-00 | Class B (According to Rule 6 of IVDR Annex VIII) |
| | | 105-004252-00 | |
| 16 | Estriol (CLIA) | 105-004253-00 | Class B (According to Rule 6 of IVDR Annex VIII) |
| | | 105-004226-00 | |
| 17 | Testosterone II (CLIA) | 105-037228-00 | Class B (According to Rule 6 of IVDR Annex VIII) |
| | | 105-037229-00 | |
| 18 | Progesterone II (CLIA) | 105-032072-00 | Class B (According to Rule 6 of IVDR Annex VIII) |
| | | 105-032073-00 | |
| 19 | Anti-Mullerian Hormone (CLIA) | 105-010711-00 | Class B (According to Rule 6 of IVDR Annex VIII) |
| | | 105-010738-00 | |
| 20 | Carcinoembryonic Antigen (CLIA) | 105-004213-00 | Class C (According to Rule 3 of IVDR Annex VIII) |
| | | 105-004240-00 | |
| 21 | Alpha fetoprotein (CLIA) | 105-004214-00 | Class C (According to Rule 3 of IVDR Annex VIII) |
| | | 105-004241-00 | |
| 22 | Cancer Antigen 125(CLIA) | 105-004215-00 | Class C (According to Rule 3 of IVDR Annex VIII) |
| | | 105-004242-00 | |
| 23 | Cancer Antigen 15-3(CLIA) | 105-004216-00 | Class C (According to Rule 3 of IVDR Annex VIII) |
| | | 105-004243-00 | |
| 24 | Carbohydrate Antigen 19-9 (CLIA) | 105-004217-00 | Class C (According to Rule 3 of IVDR Annex VIII) |
| | | 105-004244-00 | |
| 25 | Free Prostate Specific Antigen (CLIA) | 105-004218-00 | Class C (According to Rule 3 of IVDR Annex VIII) |
| | | 105-004245-00 | |
| 26 | Total Prostate Specific Antigen(CLIA) | 105-004219-00 | Class C (According to Rule 3 of IVDR Annex VIII) |
| | | 105-004246-00 | |
| 27 | Cancer Antigen 72-4(CLIA) | 105-005668-00 | Class C (According to Rule 3 of IVDR Annex VIII) |
| | | 105-005685-00 | |
| 28 | Neuron-specific enolase(CLIA) | 105-005669-00 | Class C (According to Rule 3 of IVDR Annex |

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| | | 105-005686-00 | VIII) |
| 29 | CYFRA 21-1(CLIA) | 105-005670-00 | Class C (According to Rule 3 of IVDR Annex VIII) |
| | | 105-005687-00 | |
| 30 | Pepsinogen I (CLIA) | 105-010086-00 | Class C (According to Rule 3 of IVDR Annex VIII) |
| | | 105-010096-00 | |
| 31 | Pepsinogen II (CLIA) | 105-010087-00 | Class C (According to Rule 3 of IVDR Annex VIII) |
| | | 105-010097-00 | |
| 32 | ProGRP (CLIA) | 105-010084-00 | Class C (According to Rule 3 of IVDR Annex VIII) |
| | | 105-010094-00 | |
| 33 | Squamous Cell Carcinoma Antigen (CLIA) | 105-010085-00 | Class C (According to Rule 3 of IVDR Annex VIII) |
| | | 105-010095-00 | |
| 34 | Human Epididymal Protein 4 (CLIA) | 105-010088-00 | Class C (According to Rule 3 of IVDR Annex VIII) |
| | | 105-010098-00 | |
| 35 | Carbohydrate Antigen 242 (CLIA) | 105-010089-00 | Class C (According to Rule 3 of IVDR Annex VIII) |
| | | 105-010099-00 | |
| 36 | Carbohydrate Antigen 50 (CLIA) | 105-010090-00 | Class C (According to Rule 3 of IVDR Annex VIII) |
| | | 105-010100-00 | |
| 37 | Gastrin-17 (CLIA) | 105-029892-00 | Class B (According to Rule 6 of IVDR Annex VIII) |
| | | 105-029891-00 | |
| 38 | PIVKA-II (CLIA) | 105-029894-00 | Class C (According to Rule 3 of IVDR Annex VIII) |
| | | 105-029895-00 | |
| 39 | Parathyroid hormone(CLIA) | 105-008684-00 | Class B (According to Rule 6 of IVDR Annex VIII) |
| | | 105-008689-00 | |
| 40 | Calcitonin(CLIA) | 105-008685-00 | Class C (According to Rule 3 of IVDR Annex VIII) |
| | | 105-008690-00 | |
| 41 | 25-OH-Vitamin D Total (CLIA) | 105-008681-00 | Class B (According to Rule 6 of IVDR Annex VIII) |
| | | 105-008686-00 | |
| 42 | Troponin I(CLIA) | 105-005659-00 | Class C (According to Rule 3 of IVDR Annex VIII) |
| | | 105-005676-00 | |

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| 43 | B-type natriuretic peptide(CLIA) | 105-005660-00 | Class C (According to Rule 3 of IVDR Annex VIII) |
| | | 105-005677-00 | |
| 44 | Myoglobin(CLIA) | 105-005661-00 | Class C (According to Rule 3 of IVDR Annex VIII) |
| | | 105-005678-00 | |
| 45 | Creatine kinase MB(CLIA) | 105-005662-00 | Class C (According to Rule 3 of IVDR Annex VIII) |
| | | 105-005679-00 | |
| 46 | N-terminal pro B-type natriuretic peptide (CLIA) | 105-027044-00 | Class C (According to Rule 3 of IVDR Annex VIII) |
| | | 105-027045-00 | |
| 47 | High Sensitivity Cardiac Troponin I (CLIA) | 105-028989-00 | Class C (According to Rule 3 of IVDR Annex VIII) |
| | | 105-028988-00 | |
| 48 | Insulin(CLIA) | 105-005666-00 | Class C (According to Rule 3 of IVDR Annex VIII) |
| | | 105-005683-00 | |
| 49 | C-Peptide(CLIA) | 105-005667-00 | Class C (According to Rule 3 of IVDR Annex VIII) |
| | | 105-005684-00 | |
| 50 | Cortisol(CLIA) | 105-005673-00 | Class C (According to Rule 3 of IVDR Annex VIII) |
| | | 105-005690-00 | |
| 51 | Dehydroepiandrosterone sulfate(CLIA) | 105-005674-00 | Class B (According to Rule 6 of IVDR Annex VIII) |
| | | 105-005691-00 | |
| 52 | Adrenocorticotrophic hormone(CLIA) | 105-005675-00 | Class B (According to Rule 6 of IVDR Annex VIII) |
| | | 105-005692-00 | |
| 53 | Toxoplasma gondii IgM (CLIA) | 105-012534-00 | Class C (According to Rule 3 of IVDR Annex VIII) |
| | | 105-012533-00 | |
| 54 | Toxoplasma gondii IgG (CLIA) | 105-012527-00 | Class C (According to Rule 3 of IVDR Annex VIII) |
| | | 105-012528-00 | |
| 55 | Rubella Virus IgM (CLIA) | 105-012515-00 | Class C (According to Rule 3 of IVDR Annex VIII) |
| | | 105-012516-00 | |
| 56 | Rubella Virus IgG (CLIA) | 105-012521-00 | Class C (According to Rule 3 of IVDR Annex VIII) |
| | | 105-012522-00 | |

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| 57 | Cytomegalovirus IgM (CLIA) | 105-012545-00 105-012546-00 | Class C (According to Rule 3 of IVDR Annex VIII) |
| 58 | Cytomegalovirus IgG (CLIA) | 105-012539-00 105-012540-00 | Class C (According to Rule 3 of IVDR Annex VIII) |
| 59 | Herpes Simplex Virus-1 IgG (CLIA) | 105-012503-00 105-012504-00 | Class C (According to Rule 3 of IVDR Annex VIII) |
| 60 | Herpes Simplex Virus-2 IgG (CLIA) | 105-012509-00 105-012510-00 | Class C (According to Rule 3 of IVDR Annex VIII) |
| 61 | Herpes Simplex Virus 1+2 IgM (CLIA) | 105-012491-00 105-012492-00 | Class C (According to Rule 3 of IVDR Annex VIII) |
| 62 | Herpes Simplex Virus 1+2 IgG (CLIA) | 105-012497-00 105-012498-00 | Class C (According to Rule 3 of IVDR Annex VIII) |
| 63 | Toxoplasma gondii IgG Avidity (CLIA) | 105-029863-00 105-029867-00 | Class C (According to Rule 3 of IVDR Annex VIII) |
| 64 | Cytomegalovirus IgG Avidity (CLIA) | 105-029871-00 105-029870-00 | Class C (According to Rule 3 of IVDR Annex VIII) |
| 65 | Procalcitonin(CLIA) | 105-010703-00 105-010730-00 | Class C (According to Rule 3 of IVDR Annex VIII) |
| 66 | sCD14-ST (CLIA) | 105-023903-00 105-023902-00 | Class C (According to Rule 3 of IVDR Annex VIII) |
| 67 | Aldosterone II (CLIA) | 105-031481-00 105-029848-00 | Class B (According to Rule 6 of IVDR Annex VIII) |
| 68 | Renin II (CLIA) | 105-031483-00 105-031482-00 | Class B (According to Rule 6 of IVDR Annex VIII) |
| 69 | Ferritin (CLIA) | 105-004220-00 105-004247-00 | Class C (According to Rule 3 of IVDR Annex VIII) |
| 70 | Vitamin B12(CLIA) | 105-008682-00 105-008687-00 | Class C (According to Rule 3 of IVDR Annex VIII) |
| 71 | Folate(CLIA) | 105-008683-00 | Class B (According to Rule 6 of IVDR Annex |

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| | | 105-008688-00 | VIII) |
| 72 | N-terminal Peptide of Procollagen Type III(CLIA) | 105-010717-00 105-010744-00 | Class B (According to Rule 6 of IVDR Annex VIII) |
| 73 | Collagen Type IV(CLIA) | 105-010718-00 105-010745-00 | Class B (According to Rule 6 of IVDR Annex VIII) |
| 74 | Laminin(CLIA) | 105-010715-00 105-010742-00 | Class B (According to Rule 6 of IVDR Annex VIII) |
| 75 | Hyaluronic Acid(CLIA) | 105-010716-00 105-010743-00 | Class B (According to Rule 6 of IVDR Annex VIII) |
| 76 | Human Growth Hormone (CLIA) | 105-037749-00, 105-037750-00, 105-037732-00, 105-037733-00 | Class B (According to Rule 6 of IVDR Annex VIII) |
| 77 | Insulin-like Growth Factor-1 (CLIA) | 105-037773-00, 105-037772-00, 105-037747-00, 105-037748-00 | Class B (According to Rule 6 of IVDR Annex VIII) |
| 78 | Free T3 Calibrators | 105-004277-00 | Class B (According to Rule 6 of IVDR Annex VIII) |
| 79 | Free T4 Calibrators | 105-004278-00 | Class B (According to Rule 6 of IVDR Annex VIII) |
| 80 | Total T3 Calibrators | 105-004279-00 | Class B (According to Rule 6 of IVDR Annex VIII) |
| 81 | Total T4 Calibrators | 105-004280-00 | Class B (According to Rule 6 of IVDR Annex VIII) |
| 82 | TSH Calibrators | 105-004281-00 | Class B (According to Rule 6 of IVDR Annex VIII) |
| 83 | Thyroglobulin Calibrators | 105-005914-00 | Class B (According to Rule 6 of IVDR Annex |

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| 84 | Anti-Tg Calibrators | 105-005915-00 | Class B (According to Rule 6 of IVDR Annex VIII) |
| 85 | Anti-TPO Calibrators | 105-005916-00 | Class B (According to Rule 6 of IVDR Annex VIII) |
| 86 | rT3 Calibrators | 105-010213-00 | Class B (According to Rule 6 of IVDR Annex VIII) |
| 87 | Anti-Thyrotropin Receptor Antibody Calibrators | 105-010214-00, 105-020852-00 | Class B (According to Rule 6 of IVDR Annex VIII) |
| 88 | CEA Calibrators | 105-004282-00 | Class C (According to Rule 3 of IVDR Annex VIII) |
| 89 | AFP Calibrators | 105-004283-00 | Class C (According to Rule 3 of IVDR Annex VIII) |
| 90 | CA125 Calibrators | 105-004284-00 | Class C (According to Rule 3 of IVDR Annex VIII) |
| 91 | CA15-3 Calibrators | 105-004285-00 | Class C (According to Rule 3 of IVDR Annex VIII) |
| 92 | CA19-9 Calibrators | 105-004286-00 | Class C (According to Rule 3 of IVDR Annex VIII) |
| 93 | Free PSA Calibrators | 105-004287-00 | Class C (According to Rule 3 of IVDR Annex VIII) |
| 94 | Total PSA Calibrators | 105-004288-00 | Class C (According to Rule 3 of IVDR Annex VIII) |
| 95 | CA72-4 Calibrators | 105-005919-00 | Class C (According to Rule 3 of IVDR Annex VIII) |
| 96 | NSE Calibrators | 105-005920-00 | Class C (According to Rule 3 of IVDR Annex VIII) |
| 97 | CYFRA 21-1 Calibrators | 105-005921-00 | Class C (According to Rule 3 of IVDR Annex VIII) |

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| 98 | PG I Calibrators | 105-010136-00 | Class C (According to Rule 3 of IVDR Annex VIII) |
| 99 | PG II Calibrators | 105-010137-00 | Class C (According to Rule 3 of IVDR Annex VIII) |
| 100 | ProGRP Calibrators | 105-010134-00 | Class C (According to Rule 3 of IVDR Annex VIII) |
| 101 | SCCA Calibrators | 105-010135-00 | Class C (According to Rule 3 of IVDR Annex VIII) |
| 102 | HE4 Calibrators | 105-010138-00 | Class C (According to Rule 3 of IVDR Annex VIII) |
| 103 | CA242 Calibrators | 105-010139-00 | Class C (According to Rule 3 of IVDR Annex VIII) |
| 104 | CA50 Calibrators | 105-010140-00 | Class C (According to Rule 3 of IVDR Annex VIII) |
| 105 | Gastrin-17 Calibrators | 105-029893-00 | Class B (According to Rule 6 of IVDR Annex VIII) |
| 106 | PIVKA-II Calibrators | 105-029896-00 | Class C (According to Rule 3 of IVDR Annex VIII) |
| 107 | Total β HCG Calibrators | 105-004290-00 | CLASS B (ACCORDING TO RULE 6 OF IVDR ANNEX VIII) |
| 108 | FSH Calibrators | 105-004291-00 | CLASS B (ACCORDING TO RULE 6 OF IVDR ANNEX VIII) |
| 109 | LH Calibrators | 105-004292-00 | CLASS B (ACCORDING TO RULE 6 OF IVDR ANNEX VIII) |
| 110 | Prolactin Calibrators | 105-004293-00 | Class C (According to Rule 3 of IVDR Annex VIII) |
| 111 | Estradiol Calibrators | 105-004296-00 | CLASS B (ACCORDING TO RULE 6 OF IVDR ANNEX VIII) |
| 112 | Estriol Calibrators | 105-004297-00 | CLASS B (ACCORDING TO RULE 6 OF IVDR ANNEX VIII) |

| | | | ANNEX VIII) |
|-----|--------------------------|---------------|--|
| 113 | Testosterone Calibrators | 105-004294-00 | CLASS B (ACCORDING TO RULE 6 OF IVDR ANNEX VIII) |
| 114 | Progesterone Calibrators | 105-004295-00 | CLASS B (ACCORDING TO RULE 6 OF IVDR ANNEX VIII) |
| 115 | Insulin Calibrators | 105-005917-00 | Class C (According to Rule 3 of IVDR Annex VIII) |
| 116 | C-Peptide Calibrators | 105-005918-00 | Class C (According to Rule 3 of IVDR Annex VIII) |
| 117 | Cortisol Calibrators | 105-005924-00 | Class C (According to Rule 3 of IVDR Annex VIII) |
| 118 | DHEA-S Calibrators | 105-005925-00 | CLASS B (ACCORDING TO RULE 6 OF IVDR ANNEX VIII) |
| 119 | ACTH Calibrators | 105-005926-00 | CLASS B (ACCORDING TO RULE 6 OF IVDR ANNEX VIII) |
| 120 | Troponin I Calibrators | 105-005910-00 | Class C (According to Rule 3 of IVDR Annex VIII) |
| 121 | BNP Calibrators | 105-005911-00 | Class C (According to Rule 3 of IVDR Annex VIII) |
| 122 | MYO Calibrators | 105-005912-00 | Class C (According to Rule 3 of IVDR Annex VIII) |
| 123 | CK-MB Calibrators | 105-005913-00 | Class C (According to Rule 3 of IVDR Annex VIII) |
| 124 | NT-proBNP Calibrators | 105-027049-00 | Class C (According to Rule 3 of IVDR Annex VIII) |
| 125 | hs-cTnI Calibrators | 105-031858-00 | Class C (According to Rule 3 of IVDR Annex VIII) |
| 126 | Ferritin Calibrators | 105-004289-00 | Class C (According to Rule 3 of IVDR Annex VIII) |

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| 127 | Vitamin B12 Calibrators | 105-008552-00 | Class C (According to Rule 3 of IVDR Annex VIII) |
| 128 | 25-OH-Vitamin D Total Calibrators | 105-008549-00 | CLASS B (ACCORDING TO RULE 6 OF IVDR ANNEX VIII) |
| 129 | PTH Calibrators | 105-008553-00 | CLASS B (ACCORDING TO RULE 6 OF IVDR ANNEX VIII) |
| 130 | Calcitonin Calibrators | 105-008550-00 | Class C (According to Rule 3 of IVDR Annex VIII) |
| 131 | PCT Calibrators | 105-010219-00 | Class C (According to Rule 3 of IVDR Annex VIII) |
| 132 | sCD14-ST Calibrators | 105-023905-00 | Class C (According to Rule 3 of IVDR Annex VIII) |
| 133 | ALD Calibrators | 105-011969-00 | CLASS B (ACCORDING TO RULE 6 OF IVDR ANNEX VIII) |
| 134 | Renin Calibrators | 105-012129-00 | CLASS B (ACCORDING TO RULE 6 OF IVDR ANNEX VIII) |
| 135 | Thyroid Function Multi Control | 105-007379-00 | CLASS B (ACCORDING TO RULE 6 OF IVDR ANNEX VIII) |
| | | 105-007380-00 | |
| | | 105-007371-00 | |
| | | 105-007372-00 | |
| 136 | Anti-thyroid Antibodies Control | 105-005931-00 | CLASS B (ACCORDING TO RULE 6 OF IVDR ANNEX VIII) |
| | | 105-005945-00 | |
| | | 105-005932-00 | |
| | | 105-005946-00 | |
| | | 105-010221-00 | |
| 137 | rT3 Control | 105-010231-00 | CLASS B (ACCORDING TO RULE 6 OF IVDR ANNEX VIII) |
| | | 105-010220-00 | |

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| | | 105-010240-00 105-010230-00 105-010250-00 | |
| 138 | NSE control | 105-005937-00 105-005951-00 105-005938-00 105-005952-00 | Class C (According to Rule 3 of IVDR Annex VIII) |
| 139 | Gastritis Multi Control | 105-010144-00 105-010154-00 105-010149-00 105-010159-00 | Class C (According to Rule 3 of IVDR Annex VIII) |
| 140 | PIVKA-II control | 105-031984-00 105-031983-00 105-031988-00 105-031987-00 | Class C (According to Rule 3 of IVDR Annex VIII) |
| 141 | Tumor Marker Multi Control II | 105-010146-00 105-010156-00 105-010151-00 105-010161-00 | Class C (According to Rule 3 of IVDR Annex VIII) |
| 142 | ProGRP Control | 105-010145-00 105-010155-00 105-010150-00 105-010160-00 | Class C (According to Rule 3 of IVDR Annex VIII) |
| 143 | Reproductive Multi Control | 105-008890-00 105-004266-00 105-008891-00 | Class C (According to Rule 3 of IVDR Annex VIII) |

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| | | 105-004267-00 | |
| 144 | AMH Control | 105-018808-00 105-018809-00 105-018810-00 105-018811-00 | CLASS B (ACCORDING TO RULE 6 OF IVDR ANNEX VIII) |
| 145 | Cardiac Marker Multi Control | 105-005941-00 105-005927-00 105-005942-00 105-005928-00 | Class C (According to Rule 3 of IVDR Annex VIII) |
| 146 | hs-cTnI Control | 105-031870-00 105-031861-00 105-031869-00 105-031860-00 105-031868-00 105-031856-00 | Class C (According to Rule 3 of IVDR Annex VIII) |
| 147 | NT-proBNP Control | 105-035649-00 105-035650-00 105-035738-00 105-035737-00 | Class C (According to Rule 3 of IVDR Annex VIII) |
| 148 | Immunoassay Multi Control | 105-005943-00 105-005929-00 105-005944-00 105-005930-00 | Class C (According to Rule 3 of IVDR Annex VIII) |
| 149 | ACTH Control | 105-005939-00 105-005953-00 105-005940-00 | CLASS B (ACCORDING TO RULE 6 OF IVDR ANNEX VIII) |

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| | | 105-005954-00 | |
| 150 | Metabolic Multi Control | 105-008554-00 105-008556-00 105-008555-00 105-008557-00 | Class C (According to Rule 3 of IVDR Annex VIII) |
| 151 | Liver Fibrosis Multi Control | 105-010229-00 105-010249-00 105-010239-00 105-010259-00 | CLASS B (ACCORDING TO RULE 6 OF IVDR ANNEX VIII) |
| 152 | PCT Control | 105-010228-00 105-010248-00 105-010238-00 105-010258-00 | Class C (According to Rule 3 of IVDR Annex VIII) |
| 153 | sCD14-ST Control | 105-023924-00 105-023925-00 105-023932-00 105-023933-00 | CLASS B (ACCORDING TO RULE 6 OF IVDR ANNEX VIII) |
| 154 | Hypertension Multi Control | 105-012437-00 105-012438-00 105-012439-00 105-012440-00 | CLASS B (ACCORDING TO RULE 6 OF IVDR ANNEX VIII) |
| 155 | Toxo IgG Avidity Control | 105-029872-00 105-029873-00 105-029874-00 105-029875-00 105-029876-00 | Class C (According to Rule 3 of IVDR Annex VIII) |

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| 156 | CMV IgG Avidity Control | 105-029880-00 | C |
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