



Anexo ao Certificado

Annex to Certificate

ANEXO AO CERTIFICADO NÚMERO 2006/CEP.2702

Annex to the Certificate Number

Este certificado contempla as atividades do **Instituto Português do Sangue e da Transplantação, I.P.**

This certificate contemplate the activities specified of

Bioarquivo do Banco Público de Células do Cordão Umbilical
Instalações do Serviço de Imunohemoterapia do
Centro Hospitalar Universitário São João
Bioarchive of the Public Bank of Umbilical Cells, Facilities
of the Immunohemotherapy Service of Centro Hospitalar Universitário São João
Rua Doutor Roberto Frias
4200-467 PORTO - PORTUGAL

Centro de Sangue e da Transplantação de Lisboa
Área Funcional da Transplantação
Blood and Transplantation Centre of Lisbon, Functional Area of Transplantation
Hospital Pulido Valente Alameda das Linhas de Torres, 117
1769-001 LISBOA - PORTUGAL

Centro de Sangue e da Transplantação do Porto
Área Funcional do Sangue
Blood and Transplantation Centre of Oporto, Functional Area of Blood
Rua do Bolama, 133
4200-139 PORTO - PORTUGAL

Laboratório Regional de Saúde Pública do Algarve
Dra. Laura Ayres, Laboratório de Imunohemoterapia
Regional Public Health Laboratory of Algarve, Dr. Laura Ayres,
Immunohaemotherapy Laboratory
Parque das Cidades São João da Venda
8135-014 ALMANCIL - PORTUGAL

Centro de Sangue e da Transplantação de Lisboa
Área Funcional do Sangue
Blood and Transplantation Centre of Lisbon, Functional Area of Blood
Avenida do Brasil, 53 - Pav. 17
1749-005 LISBOA - PORTUGAL

Centro de Sangue e da Transplantação de Coimbra
Blood and Transplantation Centre of Coimbra
Rua Escola Inês de Castro - São Martinho do Bispo
3040-226 COIMBRA - PORTUGAL



José Leitão
CEO

Emitido em 2023-12-28

Date of issue

Válido até 2024-05-28

Valid until





Certificado Certificate

NÚMERO 2006/CEP.2702

Number



O Sistema de Gestão da Qualidade do *The Quality Management System of* **Instituto Português do Sangue e da Transplantação, I.P.**

Avenida Miguel Bombarda, 6
1000-208 LISBOA - PORTUGAL

e dos locais apresentados em anexo
and the sites specified in annex

implementado em áreas de suporte da Coordenação Nacional da Transplantação, Coordenação Nacional do Sangue e da Medicina Transfusional e integra a Formação Técnica das Áreas do Sangue e da Transplantação. Área Funcional do Sangue: Colheita, processamento, armazenamento, distribuição e disponibilização de componentes sanguíneos humanos (incluindo plasma com redução patogénica); a partir da separação de sangue total, acondicionamento e armazenamento de plasma para tratamento por solvente detergente e para fracionamento em medicamentos derivados do plasma; testes laboratoriais de imunohematologia de rotina e referência, testes laboratoriais de rastreio serológico e genómico para agentes infeciosos, testes laboratoriais de imunologia plaquetária; gestão da distribuição de plasma solvete detergente e de medicamentos derivados do plasma nacional; controlo de qualidade de componentes sanguíneos e hemovigilância. Área Funcional da Transplantação: testes laboratoriais de imunogenética/ genética, testes laboratoriais de imunobiologia, testes laboratoriais de citometria de fluxo, testes laboratoriais de rastreio de agentes transmissíveis, testes laboratoriais de suporte à transplantação de órgãos, tecidos e células, medicina regenerativa e a outras áreas da patologia; processamento, preservação, armazenamento e distribuição de tecidos de origem humana; processamento, preservação, armazenamento e distribuição de células de sangue do cordão de origem humana, gestão do CEDACE; biovigilância, cumpre os requisitos da norma

implemented in the Support areas of the National Coordination of Transplantation, National Coordination of Blood and Transfusion Medicine and integrates the Technical Training of the Areas of Blood and Transplantation. Blood Functional Area: Collection, processing, storage, distribution and availability of human blood components (including pathogen-reduced plasma); from the separation of whole blood, packaging and storage of plasma for treatment by detergent solvent and for fractionation into plasma-derived medicines; routine and reference immunohematology laboratory tests, serological and genomic screening laboratory tests for infectious agents, platelet immunology laboratory tests; management of the distribution of detergent solvent plasma and medicines derived from national plasma; quality control of blood components and hemovigilance. Functional Area of Transplantation: immunogenetics/genetics laboratory tests, immunobiology laboratory tests, flow cytometry laboratory tests, laboratory tests for screening transmissible agents, laboratory tests to support the transplantation of organs, tissues and cells, regenerative medicine and others areas of pathology; processing, preservation, storage and distribution of tissues of human origin; processing, preservation, storage and distribution of cord blood cells of human origin, management of CEDACE; biosurveillance, meets the requirements of the standard



NP EN ISO 9001:2015

José Leitão
CEO

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IQNet

THE INTERNATIONAL CERTIFICATION NETWORK

Annex to the Certificate Nr. 2006/CEP.2702

This certificate contemplates the certified sites of

Instituto Português do Sangue e da Transplantação, I.P.

**Bioarchive of the Public Bank of Umbilical Cells,
Facilities of the Immunohemotherapy Service of
Centro Hospitalar Universitário São João**
Rua Doutor Roberto Frias
4200-467 PORTO - PORTUGAL

**Regional Public Health Laboratory of Algarve,
Dr. Laura Ayres, Immunohaemotherapy Laboratory**
Parque das Cidades São João da Venda
8135-014 ALMANCIL - PORTUGAL

**Blood and Transplantation Centre of Lisbon,
Functional Area of Transplantation**
Hospital Pulido Valente, Alameda das Linhas de Torres, 117
1769-001 LISBOA - PORTUGAL

**Blood and Transplantation Centre of Lisbon,
Functional Area of Blood**
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3040-226 COIMBRA - PORTUGAL

ISO 9001:2015

Issued on: 2023-12-28
Expires on: 2024-05-28

This attestation is directly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document

Registration Number: PT- 2006/CEP.2702


Alex Stoichitoiu
President of IQNet


José Leitão
APCER CEO



IQNet Partners*:

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THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

APCER has issued an IQNet recognized certificate that
the organization

Instituto Português do Sangue e da Transplantação, I.P.

Avenida Miguel Bombarda, 6
1000-208 LISBOA - PORTUGAL

and the sites specified in annex
has implemented and maintains a

Quality Management System
for the following scope:

Support areas of the National Coordination of Transplantation, National Coordination of Blood and Transfusion Medicine and integrates the Technical Training of the Areas of Blood and Transplantation. Blood Functional Area: Collection, processing, storage, distribution and availability of human blood components (including pathogen-reduced plasma); from the separation of whole blood, packaging and storage of plasma for treatment by detergent solvent and for fractionation into plasma-derived medicines; routine and reference immunochemistry laboratory tests, serological and genomic screening laboratory tests for infectious agents, platelet immunology laboratory tests; management of the distribution of detergent solvent plasma and medicines derived from national plasma; quality control of blood components and hemovigilance. Functional Area of Transplantation: immunogenetics/genetics laboratory tests, immunobiology laboratory tests, flow cytometry laboratory tests, laboratory tests for screening transmissible agents, laboratory tests to support the transplantation of organs, tissues and cells, regenerative medicine and others areas of pathology; processing, preservation, storage and distribution of tissues of human origin; processing, preservation, storage and distribution of cord blood cells of human origin, management of CEDACE; biosurveillance

which fulfills the requirements of the following standard

ISO 9001:2015

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Alex Stoichitoiu
President of IQNet

José Leitão
APCER CEO

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