

acreditat pentru  
CERTIFICARE



SR EN ISO/CEI 17021-1:2015  
CERTIFICAT DE ACREDITARE  
SM 004



C E R T I F I C A T

SRAC certifică organizația/ certifies the organisation

## SANTE INTERNATIONAL SA

Sediul social: Șos. Mihai Bravu, nr. 7, bl. P37 - P37A, sc. A, et. 1, ap. 4, sector 2, București

cu sediile de lucru și activitățile prezentate în anexă  
with the productive units and activities as listed in the annex

că are implementat și menține un  
**sistem de managementul calității**  
conform condițiilor din standardul

which has implemented and maintains a  
**quality management system**  
which fulfils the requirements of the standard

### SR EN ISO 13485:2016



Valabilitatea certificatului este condiționată de  
efectuarea supravegheților anuale până la data de:



nr. certificat/ certificate registration no. **197**  
data inițială a certificării/ initial certification date **29 decembrie 2023**  
data recertificării/ recertification date -  
data ultimei actualizări/ last update -  
valabil până la/ valid until **28 decembrie 2026** (cu condiția vizării anuale)  
SRAC CERT SRL, Str. Vasile Pârvan Nr. 14, Sector 1, București [www.srac.ro](http://www.srac.ro)

Director General  
Ing. Mihaela Cristea

# A N E X Ă C E R T I F I C A T



## SANTE INTERNATIONAL SA

Sediul social: Șos. Mihai Bravu, nr. 7, bl. P37 - P37A, sc. A, et. 1, ap. 4, sector 2, București

Sediul de lucru: Str. Mântuleasa, nr. 33, sector 2, București  
**pentru următoarele activități/  
for the following fields of activities**

Import și distribuție Dispozitive medicale neactive: Dispozitive medicale generale neactive, neimplantabile: Dispozitive medicale neactive pentru dezinfectare, curățare, clătire; Implanturi neactive: Implanturi neactive cardiovasculare (dispozitive de închidere defecte, valve și inele cardiace); Dispozitive medicale neactive, altele decât cele specificate anterior: ace introducatoare patch-uri electro-anatomice și accesorii pentru stimuloare și defibrilatoare cardiace. Import și distribuție Dispozitive medicale active (neimplantabile): Dispozitive medicale active generale: dispozitive pentru stimulare sau inhibare: stimuloare externe; Dispozitive medicale active (neimplantabile) altele decât cele specificate anterior: sistem de electrofiziologie și sistem de cartografiere 3 D, diverse tipuri de catetere, catetere de cartografiere 3D pentru cardiologie. Import și distribuție dispozitive medicale de diagnostic în vitro (IVD): Reactivi și produse reactive, calibratori și materiale de control pentru: Chimie Clinică, Imunochimie (Imunologie) Hematologie / Hemostază / Imunohematologie, Microbiologie, Imunologie Infecțioasă, Histologie / Citologie / Testare Genetică (biochimie și sediment urinar, Point-of-Care, plasma proteine); Instrumente de diagnostic in vitro și software (echipamente); Dispozitive medicale IVD, altele decât cele specificate anterior (microtainere, eprubete). Import și distribuție Dispozitive care încorporează / utilizează substanțe specifice / tehnologii: Dispozitive medicale care utilizează țesuturi de origine animală. Instruire utilizatori pentru dispozitive medicale. Instruire utilizatori pentru dispozitive medicale.

\*Import și distribuție Dispozitive medicale active implantabile: Dispozitive medicale active implantabile generale: Dispozitive medicale active implantabile pentru stimulare / inhibare (stimuloare, defibrilatoare); Dispozitive medicale implantabile, altele decât cele specificate anterior (dispozitive de monitorizare cardiacă)

Import and distribution Non-active medical devices: Non-active, non-implantable general medical devices: Non-active medical devices for disinfection, cleaning, rinsing; Non-active implants: Non-active cardiovascular implants (defective closures, heart valves and rings); Non-active medical devices other than those specified above: inserting needles, electro-anatomical patches and accessories for pacemakers and cardiac defibrillators. Import and distribution Active (non-implantable) medical devices: General active medical devices: stimulation or inhibition devices: external stimulators; Active (non-implantable) medical devices other than those specified above: electrophysiology system and 3D mapping system, various types of catheters, 3D mapping catheters for cardiology. Import and distribution of in vitro diagnostic (IVD) medical devices: Reagents and reactive products, calibrators and control materials for: Clinical Chemistry, Immunochemistry (Immunology) Hematology / Hemostasis / Immunohematology, Microbiology, Infectious Immunology, Histology / Cytology / Genetic Testing (Biochemistry and Urinary Sediment, Point-of-Care, Plasma Proteins); In vitro diagnostic instruments and software (equipment); IVD medical devices other than those specified above (microtainers, test tubes). Import and distribution Devices incorporating / using specific substances / technologies: Medical devices using tissues of animal origin. Medical Device User Training.

\*Import and distribution Active implantable medical devices: General implantable active medical devices: Active implantable medical devices for stimulation / inhibition (pacemakers, defibrillators); Implantable medical devices other than those specified above (cardiac monitoring devices)

\*domeniile de activitate marcate NU sunt acoperite de acreditarea RENAR. Pentru detalii suplimentare vă rugăm să consultați certificatul de acreditare pe site-ul [www.srac.ro](http://www.srac.ro)

nr. certificat/ certificate registration no. 197

Anexă eliberată la/ Annex issued on 29.12.2023

Această anexă este valabilă numai cu certificatul menționat/ This annex is valid only in connection with the mentioned certificate

Pagina/Page 1/3

# A N E X Ă C E R T I F I C A T



## SANTE INTERNATIONAL SA

Sediul social: Șos. Mihai Bravu, nr. 7, bl. P37 - P37A, sc. A, et. 1, ap. 4, sector 2, București

Sediul de lucru: Str. Pupitrului, nr. 81, sector 3, București

### **pentru următoarele activități/ for the following fields of activities**

*Import, distribuție, depozitare, service (instalare, punere în funcțiune, întreținere, reparare și instruire) Dispozitive medicale active (neimplantabile): Dispozitive medicale active generale: Dispozitive pentru circulația extra-corporală, infuzii și hemaferază; dispozitive active pentru dezinfectare și sterilizare; Software. Dispozitive de monitorizare: Dispozitive de monitorizare a parametrilor fiziologici vitali; Import, distribuție, depozitare, service (instalare, punere în funcțiune, întreținere, reparare și instruire) Dispozitive medicale de diagnostic in vitro (IVD): Instrumente de diagnostic in vitro și software (echipamente). Import, distribuție, depozitare: Dispozitive medicale neactive: Dispozitive medicale generale neactive, neimplantabile: dispozitive medicale neactive pentru dezinfectare, curățare, clătire. Import, distribuție, depozitare: Dispozitive medicale active (neimplantabile): Dispozitive medicale active (neimplantabile) altele decât cele specificate anterior: Iluminatoare de vene. Instruire utilizatori pentru dispozitive medicale. \*Import, distribuție, depozitare: Dispozitive medicale active implantabile: Dispozitive medicale active implantabile generale: dispozitive medicale active implantabile pentru stimulare / inhibare Instruire utilizatori pentru dispozitive medicale*

*Import, distribution, storage, service (installation, commissioning, maintenance, repair and training) Active (non-implantable) medical devices: General active medical devices: Devices for extra-corporeal circulation, infusions and hamapheresis; active devices for disinfection and sterilization; Software. Monitoring devices: Devices for monitoring vital physiological parameters; Import, distribution, storage, service (installation, commissioning, maintenance, repair and training) In vitro diagnostic (IVD) medical devices: In vitro diagnostic instruments and software (equipment). Import, distribution, storage: Non-active medical devices: Non-active, non-implantable general medical devices: Non-active disinfecting medical devices, cleaning, rinsing. User training for medical devices. \*Import, distribution, storage: Active medical devices (non-implantable): Active (non-implantable) medical devices other than those specified above: Vein illuminators. Import, distribution, storage: Active implantable medical devices: General active implantable medical devices: Active implantable medical devices for stimulation/inhibition User training for medical devices*

*\*domeniile de activitate marcate NU sunt acoperite de acreditarea RENAR. Pentru detalii suplimentare vă rugăm să consultați certificatul de acreditare pe site-ul [www.srac.ro](http://www.srac.ro)*

nr. certificat/ certificate registration no. **197**

Anexă eliberată la/ Annex issued on **29.12.2023**

Această anexă este valabilă numai cu certificatul menționat/ This annex is valid only in connection with the mentioned certificate

Pagina/Page 2/3

# A N E X Ă C E R T I F I C A T



## SANTE INTERNATIONAL SA

Sediul social: Șos. Mihai Bravu, nr. 7, bl. P37 - P37A, sc. A, et. 1, ap. 4, sector 2, București

Sediul de lucru: Șos. Mihai Bravu, nr. 7, bl. P37-P37A, parter, sector 2, București  
**pentru următoarele activități/  
for the following fields of activities**

*Distribuție, depozitare și comercializare Dispozitive medicale neactive: Dispozitive medicale generale neactive, neimplantabile: Dispozitive medicale neactive pentru dezinfectare, curățare, clătire; Implanturi neactive: Implanturi neactive cardiovasculare (dispozitive de închidere defecte, valve și inele cardiace); Dispozitive medicale neactive, altele decât cele specificate anterior: ace introduse patch-uri electro-anatomice și accesorii pentru stimuloare și defibrilatoare cardiace. Distribuție, depozitare și comercializare Dispozitive medicale active (neimplantabile): Dispozitive medicale active generale: dispozitive pentru stimulare sau inhibare: stimuloare externe; Dispozitive medicale active (neimplantabile) altele decât cele specificate anterior: sistem de electrofiziologie și sistem de cartografiere 3 D, diverse tipuri de catetere, catetere de cartografiere 3D pentru cardiologie. Distribuție dispozitive medicale de diagnostic in vitro (IVD): Reactivi și produse reactive, calibratori și materiale de control pentru: Chimie Clinică, Imunochimie (Imunologie) Hematologie / Hemostază / Imunohematologie, Microbiologie, Imunologie Infecțioasă, Histologie / Citologie / Testare Genetică (biochimie și sediment urinar, Point-of-Care, plasma proteine); Dispozitive medicale IVD, altele decât cele specificate anterior (microtainere, eprubete). Distribuție Dispozitive care încorporează / utilizează substanțe specifice / tehnologii: Dispozitive medicale care utilizează țesuturi de origine animală.*

*\*Distribuție, depozitare și comercializare Dispozitive medicale active implantabile: Dispozitive medicale active implantabile generale: Dispozitive medicale active implantabile pentru stimulare / inhibare (stimuloare, defibrilatoare); Dispozitive medicale implantabile, altele decât cele specificate anterior (dispozitive de monitorizare cardiacă)*

*Distribution, storage and marketing Non-active medical devices: Non-active, non-implantable general medical devices: Non-active medical devices for disinfection, cleaning, rinsing; Non-active implants: Non-active cardiovascular implants (defective closures, heart valves and rings); Non-active medical devices other than those specified above: inserting needles, electro-anatomical patches and accessories for pacemakers and cardiac defibrillators. Distribution, storage and marketing Active (non-implantable) medical devices: General active medical devices: stimulation or inhibition devices: external stimulators; Active (non-implantable) medical devices other than those specified above: electrophysiology system and 3D mapping system, various types of catheters, 3D mapping catheters for cardiology. In vitro diagnostic (IVD) medical devices distribution: Reagents and reactive products, calibrators and control materials for: Clinical Chemistry, Immunochemistry (Immunology) Hematology / Hemostasis / Immunoematology, Microbiology, Infectious Immunology, Histology / Cytology / Genetic Testing (biochemistry and urinary sediment, Point-of-Care, plasma proteins); IVD medical devices other than those specified above (microtainers, test tubes). Distribution Devices incorporating / using specific substances / technologies: Medical devices using tissues of animal origin.*

*\*Distribution, storage and marketing. Active implantable medical devices: General active implantable medical devices: Active implantable medical devices for stimulation / inhibition (pacemakers, defibrillators); Implantable medical devices other than those specified above (cardiac monitoring devices)*

*\*domeniile de activitate marcate NU sunt acoperite de acreditarea RENAR. Pentru detalii suplimentare vă rugăm să consultați certificatul de acreditare pe site-ul [www.srac.ro](http://www.srac.ro)*

nr. certificat/ certificate registration no. 197

Anexă eliberată la/ Annex issued on 29.12.2023

Această anexă este valabilă numai cu certificatul menționat/ This annex is valid only in connection with the mentioned certificate

Pagina/Page 3/3



Building trust together.

# Certificate

SRAC has issued an IQNET recognized certificate that the organization:

## SANTE INTERNATIONAL SA

Registered Office: Șos. Mihai Bravu, nr. 7, bl. P37 - P37A, sc. A, et. 1, ap. 4, sector 2, București

has implemented and maintains a  
**Quality Management System**

with the productive units and activities as listed in the annex

which fulfils the requirements of the following standard:

## EN ISO 13485 : 2016

Issued on: 2023 - 12 - 29  
First issued on: 2023 - 12 - 29  
Expires on: 2026 - 12 - 28

**Registration Number: RO - 0197**

Alex Stoichitoiu  
President of IQNET

eng. Mihaela Cristea  
SRAC General Manager



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

**IQNET Members\*:**

AENOR Spain AFNOR Certification France APCER Portugal CCC Cyprus CISQ Italy CQC China CQM China CQS Czech Republic  
Cro Cert Croatia DQS Holding GmbH Germany EAGLE Certification Group USA FCAV Brazil FONDONORMA Venezuela ICONTEC  
Colombia ICS Bosnia and Herzegovina INTECO Costa Rica IRAM Argentina JQA Japan KFQ Korea LSQA Uruguay MIRTEC Greece  
MSZT Hungary Nemko AS Norway NSAI Ireland NYCE México PCBC Poland Quality Austria Austria SII Israel SIQ Slovenia SIRIM  
QAS International Malaysia SQS Switzerland SRAC Romania TSE Türkiye YUQS Serbia

\*The list of IQNET Members is valid at the time of issue of this certificate. Updated information is available under [www.iqnet-certification.com](http://www.iqnet-certification.com)



Building  
trust  
together.

Annex 1 of 3 to IQNET Certificate Number  
RO - 0197

**SANTE INTERNATIONAL SA**

Registered Office: Șos. Mihai Bravu, nr. 7, bl. P37 - P37A, sc. A, et. 1, ap. 4, sector 2, București

Productive Unit: Str. Mântuleasa, nr. 33, sector 2, București

for the following scope:

Import and distribution Non-active medical devices: Non-active, non-implantable general medical devices: Non-active medical devices for disinfection, cleaning, rinsing; Non-active implants: Non-active cardiovascular implants (defective closures, heart valves and rings); Non-active medical devices other than those specified above: inserting needles, electro-anatomical patches and accessories for pacemakers and cardiac defibrillators. Import and distribution Active (non-implantable) medical devices: General active medical devices: stimulation or inhibition devices: external stimulators; Active (non-implantable) medical devices other than those specified above: electrophysiology system and 3D mapping system, various types of catheters, 3D mapping catheters for cardiology. Import and distribution of in vitro diagnostic (IVD) medical devices: Reagents and reactive products, calibrators and control materials for: Clinical Chemistry, Immunochemistry (Immunology) Hematology / Hemostasis / Immunohematology, Microbiology, Infectious Immunology, Histology / Cytology / Genetic Testing (Biochemistry and Urinary Sediment, Point-of-Care, Plasma Proteins); In vitro diagnostic instruments and software (equipment); IVD medical devices other than those specified above (microtainers, test tubes). Import and distribution Devices incorporating / using specific substances / technologies: Medical devices using tissues of animal origin. Medical Device User Training. Import and distribution Active implantable medical devices: General implantable active medical devices: Active implantable medical devices for stimulation / inhibition (pacemakers, defibrillators); Implantable medical devices other than those specified above (cardiac monitoring devices)

.....  
This annex is only valid in connection with the original certificate number mentioned above.

**IQNET Members\*:**

**AENOR** Spain **AFNOR Certification** France **APCER** Portugal **CCC** Cyprus **CISQ** Italy **CQC** China **CQM** China **CQS** Czech Republic  
**Cro Cert** Croatia **DQS Holding GmbH** Germany **EAGLE Certification Group** USA **FCAV** Brazil **FONDONORMA** Venezuela **ICONTEC**  
Colombia **ICS** Bosnia and Herzegovina **INTECO** Costa Rica **IRAM** Argentina **JQA** Japan **KFQ** Korea **LSQA** Uruguay **MIRTEC** Greece  
**MSZT** Hungary **Nemko AS** Norway **NSAI** Ireland **NYCE** México **PCBC** Poland **Quality Austria** Austria **SII** Israel **SIQ** Slovenia **SIRIM**  
**QAS International** Malaysia **SGS** Switzerland **SRAC** Romania **TSE** Türkiye **YUQS** Serbia

\*The list of IQNET Members is valid at the time of issue of this certificate. Updated information is available under [www.iqnet-certification.com](http://www.iqnet-certification.com)



Building  
trust  
together.

Annex 2 of 3 to IQNET Certificate Number  
**RO - 0197**

**SANTE INTERNATIONAL SA**

Registered Office: Șos. Mihai Bravu, nr. 7, bl. P37 - P37A, sc. A, et. 1, ap. 4, sector 2, București

Productive Unit: Str. Pupitrului, nr. 81, sector 3, București  
for the following scope:

Import, distribution, storage, service (installation, commissioning, maintenance, repair and training)  
Active (non-implantable) medical devices: General active medical devices: Devices for extra-corporeal circulation, infusions and hamapheresis; active devices for disinfection and sterilization; Software.  
Monitoring devices: Devices for monitoring vital physiological parameters; Import, distribution, storage, service (installation, commissioning, maintenance, repair and training) In vitro diagnostic (IVD) medical devices: In vitro diagnostic instruments and software (equipment). Import, distribution, storage: Non-active medical devices: Non-active, non-implantable general medical devices: Non-active disinfecting medical devices, cleaning, rinsing. User training for medical devices. Import, distribution, storage: Active medical devices (non-implantable): Active (non-implantable) medical devices other than those specified above: Vein illuminators. Import, distribution, storage: Active implantable medical devices: General active implantable medical devices: Active implantable medical devices for stimulation/inhibition

.....  
This annex is only valid in connection with the original certificate number mentioned above.  
.....

**IQNET Members\*:**

**AENOR** Spain **AFNOR Certification** France **APCER** Portugal **CCC** Cyprus **CISQ** Italy **CQC** China **CQM** China **CQS** Czech Republic  
**Cro Cert** Croatia **DQS Holding GmbH** Germany **EAGLE Certification Group** USA **FCAV** Brazil **FONDONORMA** Venezuela **ICONTEC**  
Colombia **ICS** Bosnia and Herzegovina **INTECO** Costa Rica **IRAM** Argentina **JQA** Japan **KFQ** Korea **LSQA** Uruguay **MIRTEC** Greece  
**MSZT** Hungary **Nemko AS** Norway **NSAI** Ireland **NYCE** México **PCBC** Poland **Quality Austria** Austria **SII** Israel **SIQ** Slovenia **SIRIM**  
**QAS International** Malaysia **SQS** Switzerland **SRAC** Romania **TSE** Türkiye **YUQS** Serbia

\* The list of IQNET Members is valid at the time of issue of this certificate. Updated information is available under [www.iqnet-certification.com](http://www.iqnet-certification.com)



Building  
trust  
together.

Annex 3 of 3 to IQNET Certificate Number  
RO - 0197

**SANTE INTERNATIONAL SA**

Registered Office: Șos. Mihai Bravu, nr. 7, bl. P37 - P37A, sc. A, et. 1, ap. 4, sector 2, București

Productive Unit: Șos. Mihai Bravu, nr. 7, bl. P37-P37A, parter, sector 2, București  
for the following scope:

Distribution, storage and marketing Non-active medical devices: Non-active, non-implantable general medical devices: Non-active medical devices for disinfection, cleaning, rinsing; Non-active implants: Non-active cardiovascular implants (defective closures, heart valves and rings); Non-active medical devices other than those specified above: inserting needles, electro-anatomical patches and accessories for pacemakers and cardiac defibrillators. Distribution, storage and marketing Active (non-implantable) medical devices: General active medical devices: stimulation or inhibition devices: external stimulators; Active (non-implantable) medical devices other than those specified above: electrophysiology system and 3D mapping system, various types of catheters, 3D mapping catheters for cardiology. In vitro diagnostic (IVD) medical devices distribution: Reagents and reactive products, calibrators and control materials for: Clinical Chemistry, Immunochemistry (Immunology) Hematology / Hemostasis / Immunohematology, Microbiology, Infectious Immunology, Histology / Cytology / Genetic Testing (biochemistry and urinary sediment, Point-of-Care, plasma proteins); IVD medical devices other than those specified above (microtainers, test tubes). Distribution Devices incorporating / using specific substances / technologies: Medical devices using tissues of animal origin. Distribution, storage and marketing. Active implantable medical devices: General active implantable medical devices: Active implantable medical devices for stimulation / inhibition (pacemakers, defibrillators); Implantable medical devices other than those specified above (cardiac monitoring devices)

.....  
This annex is only valid in connection with the original certificate number mentioned above.

**IQNET Members\*:**

**AENOR** Spain **AFNOR Certification** France **APCER** Portugal **CCC** Cyprus **CISQ** Italy **CQC** China **CQM** China **CQS** Czech Republic  
**Cro Cert** Croatia **DQS Holding GmbH** Germany **EAGLE Certification Group** USA **FAV** Brazil **FONDONORMA** Venezuela **ICONTEC**  
Colombia **ICS** Bosnia and Herzegovina **INTECO** Costa Rica **IRAM** Argentina **JQA** Japan **KFQ** Korea **LSQA** Uruguay **MIRTEC** Greece  
**MSZT** Hungary **Nemko AS** Norway **NSAI** Ireland **NYCE** México **PCBC** Poland **Quality Austria** Austria **SII** Israel **SIQ** Slovenia **SIRIM**  
**QAS International** Malaysia **SQS** Switzerland **SRAC** Romania **TSE** Türkiye **YUQS** Serbia

\* The list of IQNET Members is valid at the time of issue of this certificate. Updated information is available under [www.iqnet-certification.com](http://www.iqnet-certification.com)