



CERTIFICATO n. **13887**  
CERTIFICATE No

SI CERTIFICA CHE L'ORGANIZZAZIONE  
WE HEREBY CERTIFY THAT THE ORGANIZATION

**SANTEX S.p.A.**

IT - 20121 MILANO (MI) - VIA SAN GIOVANNI SUL MURO 1

NEI SEGUENTI SITI / IN THE FOLLOWING SITES

IT - 36040 SAREGO (VI) - VIA MASSINA 10

IT - 36040 MELEDO DI SAREGO (VI) - VIA ALBERTO SANTURRO 2

IT - 20121 MILANO (MI) - VIA SAN GIOVANNI SUL MURO 1

HA ATTUATO E MANTIENE UN SISTEMA DI GESTIONE SICUREZZA CHE E' CONFORME ALLA NORMA  
HAS IMPLEMENTED AND MAINTAINS A SAFETY MANAGEMENT SYSTEM WHICH COMPLIES WITH THE FOLLOWING STANDARD

**OHSAS 18001:2007**

PER LE SEGUENTI ATTIVITA' / FOR THE FOLLOWING ACTIVITIES

SETTORE  
CODE

**IAF 4, 29, 35, 7**

VEDASI ALLEGATO/ SEE ANNEX

Certificazione rilasciata in conformità al Regolamento Tecnico SINCERT RT 12

IL PRESENTE CERTIFICATO E' SOGGETTO AL RISPETTO DEL REGOLAMENTO PER LA CERTIFICAZIONE DEI SISTEMI DI GESTIONE  
THE USE AND THE VALIDITY OF THE CERTIFICATE SHALL SATISFY THE REQUIREMENTS OF THE RULES FOR THE CERTIFICATION OF MANAGEMENT SYSTEMS

IL PRESENTE CERTIFICATO NON E' DA RITENERSI VALIDO SE NON ACCOMPAGNATO DAL RELATIVO ALLEGATO  
THIS CERTIFICATE IS NOT VALID WITHOUT THE RELATIVE ANNEX

PRIMA EMISSIONE **19/03/2009**  
FIRST ISSUE  
DATA DELIBERA **13/02/2018**  
DECISION DATE  
DATA SCADENZA **15/02/2021**  
EXPIRY DATE  
EMISSIONE CORRENTE **13/02/2018**  
ISSUE DATE

CERTIQUALITY S.r.l. - IL PRESIDENTE  
Via G. Giardino 4 - 20123 MILANO (MI) - ITALY



IQNet, the association of the world's first class certification bodies, is the largest provider of management System Certification in the world. IQNet is composed of more than 30 bodies and counts over 150 subsidiaries all over the globe.

For information concerning the validity of the certificate, you can visit the site [www.certiquality.it](http://www.certiquality.it)

The validity this certificate depends on annual audit and on a complete review every three years of the Management System



SGO n. 005 A SSI N. 007 D  
SBA n. 001 D SGE N. 001 M  
SCR n. 002 F ISP N. 008 D  
ESM n. 006 I EMAS N. 005 P  
PRD n. 008 B ITX N. 004 L  
GAP n. 003 H  
FRS n. 000 C

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC  
Signatory of EA, IAF and ILAC Mutual Recognition Agreements



[www.cisq.com](http://www.cisq.com)

CISQ è la Federazione Italiana di Organismi di Certificazione dei sistemi di gestione aziendale. CISQ is the Italian Federation of management system Certification Bodies.



CISQ is a member of



THE INTERNATIONAL CERTIFICATION NETWORK  
www.iqnet-certification.com

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ALLEGATO AL CERTIFICATO n. **13887**  
ANNEX TO CERTIFICATE No

## SANTEX S.p.A.

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*The validity this certificate depends on annual audit and on a complete review every three years of the Management System.*

### ATTIVITA' / ACTIVITIES

Ricerca e sviluppo, manutenzione, ai fini della produzione di: dispositivi medici sterili e non sterili in tessuto di cotone e tessuto non tessuto attraverso le fasi di preparazione tessitura (cardatura, orditura, imbozzimatura), tessitura, idrofilizzazione, impregnazione (iodoformio e vioformio), lavorazione del tessuto (taglio e/o piegatura e/o cucitura) confezionamento e sterilizzazione, produzione di dispositivi per l'ortopedia (gessate, ovatta, maglia tubolare) e dispositivi per bendaggi e fasciature, produzione assemblaggio di set o kit o pacchi procedurali con accessori, set chirurgici specialistici, monoteli chirurgici specialistici con film da incisione, telini da incisione, dispositivi medici monouso per sala operatoria; indumenti e dispositivi di protezione, teleria per sala operatoria, set specialistici per il sito di Sarego.

Ricerca e sviluppo e manutenzione, ai fini della produzione di: dispositivi medici per l'incontinenza, assorbenti igienici, pannolini per bambino e prodotti per l'igiene attraverso le fasi di macinazione cellulose, formatura materassino, accoppiamento, assemblaggio accessori e imballaggio. Commercializzazione di dispositivi medici. Progettazione ed erogazione di servizi di distribuzione ed assistenza pre-post vendita per i dispositivi medici per il sito di Meledo.

*Research and development, maintenance, for the production of: sterile and non-sterile medical devices in cotton fabric and nonwoven fabric through processes of weaving preparation (carding, warping, sizing), weaving, hydrophilization, impregnation (iodoform and vioform), fabric processing (cutting and / or folding and / or sewing) packaging and sterilization, production of orthopaedics devices (plaster bandages, wadding, tubular mesh) and devices for bandages and dressings, production assembling of sets or kits or procedural packs with accessories, specialty surgical sets, specialty surgical single-drapes with incision film, incision drapes, disposable medical devices for operating room; clothing and protective equipment, drapes for operating room, specialty sets for the site of Sarego. Research and development and maintenance, for the production of: medical devices for incontinence, sanitary towels, baby napkins and hygiene products, through processes of cellulose grinding, pad forming, coupling, accessory assembling and packaging. Sale of medical devices. Planning and provision of distribution services and pre- and after-sale services for medical devices for the site of Meledo.*

IL PRESENTE ALLEGATO NON E' DA RITENERSI VALIDO SE NON ACCOMPAGNATO DAL RELATIVO CERTIFICATO  
THIS ANNEX IS NOT VALID WITHOUT THE RELEVANT CERTIFICATE

PRIMA EMISSIONE **19/03/2009**  
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Via G. Giardino 4 - 20123 MILANO (MI) - ITALY



SGQ n. 008 A SSI N. 007 G  
SGA n. 001 D SGE N. 001 M  
SER n. 002 F ISM N. 006 O  
FSM n. 006 I EMAS N. 003 P  
PRD n. 005 B ITC N. 004 L  
DAP n. 003 H  
FRS n. 100 C

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THE INTERNATIONAL CERTIFICATION NETWORK

# CERTIFICATE

**CISQ/CERTIQUALITY S.r.l.**

has issued an IQNet recognised certificate that the organization:

**SANTEX S.p.A.**

IT - 20121 MILANO (MI) - VIA SAN GIOVANNI SUL MURO 1

for the following scope

*See annex*

has implemented and maintains a

**Safety Management System**

which fulfills the requirements of the following standard

**OH SAS 18001:2007**

Issued on: **2018-02-13**

First issued on: **2009-03-19**

Expires on: **2021-02-15**

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

*Registration number:* **IT-62015**



*Alex Stoichitoiu*  
President of IQNET



*Ing. Claudio Provetti*  
President of CISQ

**IQNet Partners\*:**

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 FCAV Brazil  
FONDONORMA Venezuela ICONTEC Colombia Inspecta Sertifointi Oy Finland INTECO Costa Rica  
IRAM Argentina JQA Japan KFQ Korea MIRTEC Greece MSZT Hungary Nemko AS Norway NSAI Ireland  
NYCE-SIGE México PCBC Poland Quality Austria Austria RR Russia SII Israel SIQ Slovenia  
SIRIM QAS International Malaysia SQS Switzerland SRAC Romania TEST St Petersburg Russia TSE Turkey YUQS Serbia  
IQNet is represented in the USA by: AFNOR Certification, CISQ, DQS Holding GmbH and NSAI Inc.



THE INTERNATIONAL CERTIFICATION NETWORK

*ANNEX 1 TO IQNET CERTIFICATE NUMBER IT-62015*

## **SANTEX S.p.A.**

### Field of scope

Research and development, maintenance, for the production of: sterile and non-sterile medical devices in cotton fabric and nonwoven fabric through processes of weaving preparation (carding, warping, sizing), weaving, hydrophilization, impregnation (iodoform and vioform), fabric processing (cutting and / or folding and / or sewing) packaging and sterilization, production of orthopaedics devices (plaster bandages, wadding, tubular mesh) and devices for bandages and dressings, production assembling of sets or kits or procedural packs with accessories, specialty surgical sets, specialty surgical single-drapes with incision film, incision drapes, disposable medical devices for operating room; clothing and protective equipment, drapes for operating room, specialty sets for the site of Sarego. Research and development and maintenance, for the production of: medical devices for incontinence, sanitary towels, baby napkins and hygiene products, through processes of cellulose grinding, pad forming, coupling, accessory assembling and packaging. Sale of medical devices. Planning and provision of distribution services and pre- and after-sale services for medical devices for the site of Meledo.