



ISTITUTO DI CERTIFICAZIONE DELLA QUALITÀ
www.certiquality.it

CERTIFICATO n. **10292**
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

NELLE SEGUENTI UNITA' OPERATIVE / IN THE FOLLOWING OPERATIVE UNITS

IT - 36040 SAREGO (VI) - VIA MASSINA 10

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

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

UNI CEI EN ISO 13485:2012

PER LE SEGUENTI ATTIVITÀ / FOR THE FOLLOWING ACTIVITIES

VEDASI ALLEGATO/ SEE ANNEX

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

PRIMA EMISSIONE
FIRST ISSUE **22/02/2006**
EMISSIONE CORRENTE
CURRENT ISSUE **24/05/2016**
DATA SCADENZA
EXPIRY DATE **29/01/2018**

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

CISQ è la Federazione Italiana di
Organismi di Certificazione dei
sistemi di gestione aziendale.

CISQ is the Italian Federation
of management system
Certification Bodies.



SGQ N° 008A PRD N° 009B
SGA N° 001D DAP N° 003H
SCR N° 002F SSI N° 007G
FSM N° 006I SGE N° 001M

Membro degli accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreement

Per informazioni sulla validità del
certificato, visitare il sito
www.certiquality.it

For information concerning the validity
of the certificate, you can visit the site
www.certiquality.it

La validità del presente certificato è
subordinata a sorveglianza periodica
annuale ed al riesame completo del
Sistema di Gestione con periodicità
triennale.

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

CISQ is a member of



THE INTERNATIONAL CERTIFICATION NETWORK
www.iqnet-certification.com

*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.*



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ALLEGATO AL CERTIFICATO n. **10292**
ANNEX TO CERTIFICATE No

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.

SANTEX S.p.A.

ATTIVITÀ / ACTIVITIES

Progettazione, produzione e vendita di dispositivi medici sterili e non sterili in tessuto di cotone e tessuto non tessuto (garze ed affini) per medicazione ed uso chirurgico, dispositivi medici per la medicazione trattati allo jodoformio o al vioformio, dispositivi medici monouso per sala operatoria, pacchi procedurali sterili, kit specialistici sterili e non sterili, teleria sterile e non sterile per sala operatoria con o senza film da incisione, indumenti e dispositivi di protezione sterili e non sterili, ovatta di cotone, ovatta ortopedica, bende gessate, garza amidata, maglia tubolare, rete elastica, rulli, bende, bende orlate, compresse oculari, prodotti ad assorbenza per incontinenza. Commercializzazione di dispositivi medici. Progettazione ed erogazione di servizi di distribuzione, assistenza, pre e postvendita, consulenza infermieristica e servizi di relazione con clienti ed utenti anche tramite call-center per dispositivi medici.

Design, manufacturing and sale of medical devices sterile and non-sterile: cotton fabric and non-woven fabric made (gauzes and similar) for medication and surgical use; wound care medical devices treated with iodoform or vioform, disposable medical devices for the operating room, sterile procedural packs, sterile and non-sterile specialty kits, sterile and non-sterile drapes for operating room with or without film by etching, clothing and protective equipment sterile and non-sterile, cotton wool, orthopaedic polyester wadding, plaster of Paris bandages, starched gauze, tubular mesh, elastic tubular mesh, gauze rolls, bandages, hemmed bandages, eye swabs, absorbent products for incontinence. Trade of medical devices. Design and provision of distribution services, assistance, pre and after-sale consulting and nurse advisory, customer-care and user-care services including via call-centre for medical devices.

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

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



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THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

IQNet and its partner
CISQ/CERTIQUALITY S.r.l.

SANTEX S.p.A.

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

has implemented and maintains a

Quality Management System

which fulfills the requirements of the following standard

ISO 13485:2003

for the following activities

See annex

in the following operative units

IT - 36040 SAREGO (VI) - VIA MASSINA 10

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

Issued on: **2016-05-24**

Certified since: **2006-02-22**

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Registration number: **IT-41062**



Michael Drechsel

President of IQNET



Ing. Claudio Provetti

President of CISQ

IQNet Partners*:

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THE INTERNATIONAL CERTIFICATION NETWORK

ANNEX 1 TO IQNET CERTIFICATE NUMBER IT-41062

SANTEX S.p.A.

Field of activity

Design, manufacturing and sale of medical devices sterile and non-sterile: cotton fabric and non-woven fabric made (gauzes and similar) for medication and surgical use; wound care medical devices treated with iodoform or vioform, disposable medical devices for the operating room, sterile procedural packs, sterile and non-sterile specialty kits, sterile and non-sterile drapes for operating room with or without film by etching, clothing and protective equipment sterile and non-sterile, cotton wool, orthopaedic polyester wadding, plaster of Paris bandages, starched gauze, tubular mesh, elastic tubular mesh, gauze rolls, bandages, hemmed bandages, eye swabs, absorbent products for incontinence. Trade of medical devices. Design and provision of distribution services, assistance, pre and after-sale consulting and nurse advisory, customer-care and user-care services including via call-centre for medical devices.

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