



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 QUALITA' CHE E' CONFORME ALLA NORMA
 HAS IMPLEMENTED AND MAINTAINS A QUALITY MANAGEMENT SYSTEM WHICH COMPLIES WITH THE FOLLOWING STANDARD

UNI CEI EN ISO 13485:2016

PER LE SEGUENTI ATTIVITA' / FOR THE FOLLOWING ACTIVITIES

VEDASI ALLEGATO/ SEE ANNEX

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 **22/02/2006**
 FIRST ISSUE
 DATA DELIBERA **22/01/2018**
 DECISION DATE
 DATA SCADENZA **28/01/2021**
 EXPIRY DATE
 EMISSIONE CORRENTE **22/01/2018**
 ISSUE DATE

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



SGQ	n.	008	A	SSI	N	007	G
SGA	n.	001	D	SGE	N	001	M
SCR	n.	002	F	ISP	N	006	O
ERM	n.	006	I	EMAS	N	008	P
PRD	n.	008	B	ITK	N	004	L
DAP	n.	003	H				
PRS	n.	100	C				

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

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.

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

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



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.



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Pagina 1/1
Page

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

SANTEX S.p.A.

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

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

ATTIVITA' / 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 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, 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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SGQ n. 009 A SSI N. 007 B
SGA n. 001 D SGE N. 001 M
SGR n. 002 F ISP N. 006 D
FSM n. 005 I EMAS N. 008 P
PRD n. 008 B ITX N. 004 L
DAP n. 003 H
PRS n. 100 C

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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.



THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

CISQ/CERTIQUALITY S.r.l.

as an IQNet Partner hereby states 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

Quality Management System

which fulfills the requirements of the following standard

ISO 13485:2016

Issued on: **2018-01-22**

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

for the validity date, please refer to the original Certificate* issued by CISQ/Certiquality s.r.l.

Registration number: **IT-41062**



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

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

** The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under www.iqnet-certification.com



THE INTERNATIONAL CERTIFICATION NETWORK

ANNEX 1 TO IQNET CERTIFICATE NUMBER IT-41062

SANTEX S.p.A.

Field of scope

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, 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.

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