



Reg. Number	17140 - M	Valid from	2024-01-24
First issue date	2006-02-22	Last change date	2024-01-24
Valid until	2027-01-28		

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Quality Management System Certificate UNI CEI EN ISO 13485:2021

We certify that the Quality Management System of the Organization:

SANTEX S.p.A.

is in compliance with the Standard UNI CEI EN ISO 13485:2021 for the following products/services:

Production management and placing on the market of sterile and non-sterile medical devices for dressing and surgical use.

Production management and placing on the market of not active, not implantable class I orthopaedic medical devices.

Design, production and placing on the market of incontinence medical devices.

Commercialization of non-active, non-implantable general medical devices.

Design and supply of distribution services, pre- and post-sale assistance, nurse advisory services, and user and customer service, including call-center for incontinence medical devices.

Contract manufacturing of incontinence medical devices.

Medical Devices Division Manager

Alessia Frabetti

The maintaining of the certification is subject to annual surveillance and dependent on the observance of Kiwa Cermet Italia contractual requirements.

The date of issuance of this certificate is the date of first issue by another accredited body.

This certificate is composed of 2 pag. The following technical datasheet provides details concerning the scope of certification.

SANTEX S.p.A.

Registered Headquarters

Via San Giovanni sul Muro, 1 20121 Milano Italia

Certified sites

Refer to the attached Technical Data Sheet for details of the locations



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Kiwa Cermet Italia S.p.A.
Single member company, subject to the management and coordination of Kiwa Italia Holding S.r.l.
Via Cadriano, 23
40057 Granarolo dell'Emilia (BO)
Tel +39.051.459.3.111
Fax +39.051.763.382
E-mail: info@kiwacermet.it
www.kiwa.it



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Data sheet attached to the Certificate
UNI CEI EN ISO 13485:2021

SANTEX S.p.A.
Certified sites:

Via San Giovanni sul Muro, 1 20121 Milano Italia

Via Massina, 10 36040 Sarego (VI) Italia

Via Alberto Santurro, 2 - frazione Meledo 36040 Sarego (VI) Italia

CERTIFICATE

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