



Reg. Number	17140 - M	Valid From	2021-01-27
First issue date	2006-02-22	Last change date	2023-05-31
Valid Until	2024-01-28		

Previous expiry date

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Quality Management System Certificate ISO 13485:2016

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 planning and management and placing on the market of sterile and non-sterile medical devices in cotton fabric and non-woven fabric (gauze and similar) for dressing and surgical use, disposable medical devices for the operating room, sterile procedure packs, sterile and non-sterile specialized kits, sterile and non-sterile surgical drapes for the operating room with or without incision film, sterile and non-sterile clothing and protective equipment, cotton wool, orthopaedic wadding, plaster bandages, starched gauze, cotton stokinette roll, tubular elastic net, rolls, bandages, hemmed bandages, eye pads and incontinence aids. Commercialization of medical devices in the field of dressing, surgery and incontinence. Design and supply of distribution services, pre- and post-sale assistance, nurse advisory services, and user and customer service, including a medical device call centre. Contract manufacturing of incontinence aids.

President
Giampiero Belcredi

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

The date of issue of this certificate corresponds to the date of first issue by another accredited body.

This certificate consists of 2 pages. Details of the processes/services carried out by the individual organisations in the Group can be found in the attached data sheet and in the relevant certificate no. 17140-HC-M issued in support of this certificate.

Kiwa Cermet Italia S.p.A.
Società con socio unico,
soggetta all'attività di
direzione e coordinamento di
Kiwa Italia Holding Srl
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

SANTEX S.p.A.

Registered Headquarters

- Via San Giovanni sul Muro, 1 20121 Milano Italia

Certified Sites

- Via San Giovanni sul Muro, 1 20121 Milano Italia

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

- Via Massina, 10 36040 Sarego (VI) Italia



SGQ N° 007A



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Data sheet attached to the Certificate ISO 13485:2016

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SANTEX HC S.r.l.

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

Contract manufacturing of incontinence aids.

President

Giampiero Belcredi

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CERMET



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