

Certificate

Certificate 3686 GROUP - M



Valid from 2024-03-21 Last change date 2026-05-18
First issue date 2003-03-24 Valid until 2027-03-23

ISO 13485:2016

Quality Management System Certificate

We certify that the Quality Management System of the Organization:

GRUPPO MEDICA

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

Management of design, production and placing on the market of active medical devices for monitoring, blood treatment and perfusion. Design, management of production and placing on the market of non-active medical devices for urology, gastroenterology, blood treatment, ultrafiltration and perfusion. Marketing of general non-active, non-implantable medical devices and general active medical devices. Placing on the market of systems and procedure packs. Production of non-active medical devices for blood treatment and ultrafiltration according to customer specifications. Molding of plastic components for medical devices according to customer specifications. Assembling of non-active, non-implantable medical devices according to customer specifications. Design and production of active medical devices for monitoring, blood treatment and perfusion according to customer specifications. Manufacture of hollow-fiber membranes for filtration and purification in the medical device sector, tailored to the customer specifications.

Kiwa Cermet Italia S.p.a.
Medical Devices
Director
Alessia Frabetti

The maintaining of the certification is subject to annual surveillance and dependent on the observance of Kiwa Cermet Italia contractual requirements.
This certificate is composed of 3 pag. The following technical sheet provides details of the scope of certification.

GRUPPO MEDICA

Registered Headquarters

Via degli Artigiani, 7 41036 Medolla (MO)

Certified sites

For details on the sites, please refer to the attached Technical Data Sheet

Kiwa Cermet Italia S.p.A.
Società con socio unico,
soggetta all'attività di direzione e
coordinamento di Kiwa Italia
Holding S.r.l.
Via Cadrano, 23
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www.kiwa.it



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Data sheet attached to the Certificate ISO 13485:2016

GRUPPO MEDICA

Certified sites:

Via degli Artigiani, 7 41036 MEDOLLA (MO)

Management of design, production and placing on the market of active medical devices for monitoring, blood treatment and perfusion. Design, management of production and placing on the market of non-active medical devices for urology, gastroenterology, blood treatment, ultrafiltration and perfusion. Marketing of general non-active, non-implantable medical devices and general active medical devices. Placing on the market of systems and procedure packs. Production of non-active medical devices for blood treatment and ultrafiltration according to customer specifications. Molding of plastic components for medical devices according to customer specifications. Assembling of non-active, non-implantable medical devices according to customer specifications. Design and production of active medical devices for monitoring, blood treatment and perfusion according to customer specifications. Manufacture of hollow-fiber membranes for filtration and purification in the medical device sector, tailored to the customer specifications.

Via degli Artigiani, 7 41036 Medolla (MO)

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Via degli Artigiani, 5 41036 MEDOLLA (MO)

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GRUPPO MEDICA

Certified sites:

Via degli Artigiani, 13 41036 MEDOLLA (MO)

Depot.

Via Posta Vecchia, 28 41037 Mirandola (MO)

Warehouse.

Via della Beverara 46/D 40100 Bologna

Customer-related processes (tender management).

Via Centauro, 24 09016 Iglesias (SU)

Production of non-active medical devices for blood treatment and ultrafiltration according to customer specifications.

Via L. Cazzuoli 43 41037 Mirandola (MO)

Design and production of active medical devices for monitoring, blood treatment and perfusion according to customer specifications.

Via L. Cazzuoli, 37 41037 MIRANDOLA (MO)

Warehouse.

Via degli Artigiani 38/40 41036 MEDOLLA (MO)

Mechanical processing.

5610 Rowland Road, Ste 145 55343 Minnetonka (MN)

Manufacture of hollow-fiber membranes for filtration and purification in the medical device sector, tailored to the customer specifications.

Espace Industriel El Azib - Lot 96, 97, 98 - Menzel Jemil 7026 Bizerte

Molding of plastic components for medical devices according to customer specifications.
Assembling of non-active, non-implantable medical devices according to customer specifications.