



| Reg. Number      | 3686 GROUP - A | Valid from       | 2024-03-21  |
|------------------|----------------|------------------|-------------|
| First issue date | 2003-03-24     | Last change date | 2024-03-21  |
| Valid until      | 2027-03-23     | IAF Sector       | 19, 14, 29a |

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# Quality Management System Certificate ISO 9001:2015

We certify that the Quality Management System of the Organization:

#### GRUPPO MEDICA

is in compliance with the Standard UNI EN ISO 9001:2015 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.

Design, management of production and placing on the market of filters and components for purification and filtration systems.

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

Production of filters and components for purification and filtration systems. 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.

Design, production and placing on the market of equipment for assembly and testing of 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.

Details of the processes/services carried out at the individual sites listed above are contained in the relevant certificates nor.3686 ME-A; 3686 MM-A; 3686 SM-A; 3686 TE-A

This certificate is composed of 4 pag. The following technical datasheet provides details concerning the scope of certification.

GRUPPO MEDICA Certified sites

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





MS Nº 0007MS

Kiwa Cermet Italia S.p.A. Single member company, subject to the management and coordination of Kiwa Italia Holding S.r.I. Via Cadriano, 23 40057 Granarolo dell'Emilia (BO) Tel +39.051.459.3.111

Fax +39.051.763.382

www.kiwa.it

E-mail: info@kiwacermet.it





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### Data sheet attached to the Certificate ISO 9001:2015

GRUPPO MEDICA Certified sites:

MEDICA S.p.A. Via degli Artigiani, 7 41036 Medolla (MO) Italia

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. Design, management of production and placing on the market of filters and components for purification and filtration systems.

MEDICA S.p.A. Via degli Artigiani, 5 41036 Medolla (MO) Italia

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. Design, management of production and placing on the market of filters and components for purification and filtration systems.

MEDICA S.p.A. Via degli Artigiani, 13 41036 Medolla (MO) Italia

Depot.

MEDICA S.p.A. Via della Beverara 46/D 40100 Bologna Italia

Customer-related processes (tender management).

Kiwa Cermet Italia S.p.A. Single member company, subject to the management and coordination of Kiwa Italia Holding S.r.I. Via Cadriano, 23 40057 Granarolo dell'Emilia (BC) Tel +30.051.459.3.111 Fax +39.051.763.382 E-mai: info@kiwacermet.it

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Medical Devices Division Manager Alessia Frabetti

desio Frabelli





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## Data sheet attached to the Certificate ISO 9001:2015

GRUPPO MEDICA Certified sites:

MEDICA S.p.A. Via Posta Vecchia, 28 41037 Mirandola (MO) Italia

Warehouse.

SAR-MED S.r.I. Via Centauro, 24 09016 Iglesias (SU) Italia

Production of non-active medical devices for blood treatment and ultrafiltration according to customer specifications. Production of filters and components for purification and filtration systems. according to customer specifications.

TECNOIDEAL S.r.I. Via L. Cazzuoli 43 41037 Mirandola (MO) Italia

Design and production of active medical devices for monitoring, blood treatment and perfusion according to customer specifications. Design, production and placing on the market of equipment for assembly and testing of medical devices.

TECNOIDEAL S.r.I. Via L. Cazzuoli, 37 41037 Mirandola (MO) Italia

Warehouse.

TECNOIDEAL S.r.I. Via degli Artigiani 38/40 41036 Medolla (MO) Italia

Mechanical processing.

TECNOIDEAL S.r.I. Via L. Cazzuoli 40 41037 Mirandola (MO) Italia

Design and manufacture of equipment for the assembly and testing of medical devices,

Medical Devices Division Manager Alessia Frabetti

desio Frabelli





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GRUPPO MEDICA Certified sites:

MEDICA MÉDITERRANÈE S.a.r.I. Espace Industriel El Azib - Lot 96, 97, 98 - Menzel Jemil 7026 Bizerte Tunisia

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

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