

## Certificate 3686 GROUP - A



Valid from 2024-03-21 Last change date 2026-05-18  
First issue date 2003-03-24 Valid until 2027-03-23  
IAF Sector 19, 29, 14

### ISO 9001:2015

### Quality Management System Certificate

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. Manufacturing of hollow fibers for filtration and purification in medical and industrial applications, tailored to 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 4 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 Cadriano, 23  
40057 - Granarolo dell'Emilia (BO)  
T. +39. 051.4593.111  
F. +39. 051.763.382  
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## Data sheet attached to the Certificate ISO 9001:2015

### 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. 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. Manufacturing of hollow fibers for filtration and purification in medical and industrial applications, tailored to customer specifications.

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

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

### GRUPPO MEDICA

#### Certified sites:

##### **Via degli Artigiani, 5 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. Design, management of production and placing on the market of filters and components for purification and filtration systems.

##### **Via degli Artigiani, 13 41036 MEDOLLA (MO)**

Depot.

##### **Via della Beverara 46/D 40100 Bologna**

Customer-related processes (tender management).

##### **Via Posta Vecchia, 28 41037 Mirandola (MO)**

Warehouse.

##### **Via Centauro, 24 09016 Iglesias (SU)**

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.

##### **Via L. Cazzuoli 43 41037 Mirandola (MO)**

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.

##### **Via L. Cazzuoli, 37 41037 MIRANDOLA (MO)**

Warehouse.

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

**GRUPPO MEDICA**

**Certified sites:**

**Via degli Artigiani 38/40 41036 MEDOLLA (MO)**

Mechanical processing.

**Via L. Cazzuoli 40 41037 MIRANDOLA (MO)**

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

**5610 Rowland Road, Ste 145 55343 Minnetonka (MN)**

Manufacturing of hollow fibers for filtration and purification in medical and industrial applications, tailored to 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.