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Reg. Number	3686 GROUP - M	Valid from	2024-03-21
First issue date	2003-03-24	Last change date	2024-03-21
Valid until	2027-03-23		

CERTIFICATE

Quality Management System Certificate

UNI CEI EN ISO 13485:2021

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.

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-M; 3686 MM-M; 3686 SM-M; 3686 TE-M
This certificate is composed of 3 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

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

MS N° 0007MS

CERTIFICATE

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Data sheet attached to the Certificate

UNI CEI EN ISO 13485:2021

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.

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.

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

Depot.

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

Warehouse.

Medical Devices Division Manager
Alessia Frabetti

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

GRUPPO MEDICA
Certified sites:

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

Customer-related processes (tender management).

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

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

TECNOIDEAL S.r.l. 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.

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

Warehouse.

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

Mechanical processing.

MEDICA MÉDITERRANÉE S.a.r.l. 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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C.C.I.A.A. R.E.A. 229672

MS N° 0007MS