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|------------------|------------|------------------|------------|
| Reg. Number      | 3686 - M   | Valid From       | 2021-03-22 |
| First issue date | 2003-03-24 | Last change date | 2021-03-22 |
| Valid Until      | 2024-03-23 |                  |            |

Previous expiry date

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Quality Management System Certificate

## ISO 13485:2016

We certify that the Quality Management System of the Organization:

### MEDICA S.p.A.

Is in compliance with the standard UNI CEI EN ISO 13485:2016 for the following products/services:

Design and production of active medical devices for monitoring, blood treatment and organ perfusion. Design and production of non-active medical devices for urology, gastroenterology, blood treatment and ultrafiltration. Molding of plastic components for medical devices. Sterilization with ethylene oxide of non-active medical devices. Marketing of general non-active, non-implantable medical devices, general active medical devices.

Chief Operating Officer  
Giampiero Belcredi

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

Refer to quality manual for details of exclusion of UNI CEI EN ISO 13485:2016 requirements.

This certificate is composed of 2 pages. The following data sheet provides application field details.

#### GRUPPO MEDICA

##### Registered Headquarters

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

##### Certified Sites

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

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

MEDICA S.p.A. - Via Posta Vecchia, 23 41037 Mirandola ( MO ) Italy

MEDICA MEDITERRANÉE s.a.r.l. - Z.I. Menzel Jemil, lot n. 53 bis 7080 7080 Bizerte Tunisia

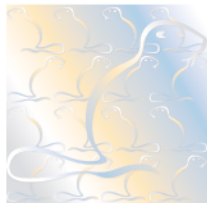
SAR-MED S.r.l. - Via Centauro, 16 09016 Iglesias ( SU ) Italy

SAR-MED S.r.l. - Via Centauro, 6 09016 Iglesias ( SU ) Italy

TECNOIDEAL S.r.l. - Via L. Cazzuoli 43 41037 Mirandola ( MO ) Italy

Kiwa Cermet Italia S.p.A.  
Società con socio unico,  
soggetta all'attività di  
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Data sheet attached to the Certificate

## ISO 13485:2016

| Operational Unit             | Application field  |
|------------------------------|--|
| Medica S.p.A.                | Design and production of active medical devices for monitoring, blood treatment and organ perfusion. Design and production of non-active medical devices for urology, gastroenterology, blood treatment. Marketing of general non-active, non-implantable medical devices, general active medical devices. |
| Sar-med S.r.l.               | Production of non-active medical devices for hemodialysis, catheters and accessories. Production of non-active medical devices for blood treatment and ultrafiltration according to customer specifications.   |
| Medica Mediterranée S.a.r.l. | Molding of plastic components for medical devices according to customer specifications. Assembling of non-active medical devices according to customer specifications. Sterilization with ethylene oxide of non-active medical devices.  |
| Tecnoideal S.r.l.            | Design and production of active medical devices for monitoring, blood treatment and organ perfusion according to customer specifications.  |

Chief Operating Officer  
Giampiero Belcredi

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**CERMET**



SGQ N° 007A