

Reg. Number	3686 - A	Valid From	2021-03-22
First issue date	2003-03-24	Last change date	2021-03-22
Valid Until	2024-03-23	IAF Sector	19, 14, 29

Previous expiry date

Page 1 of 2

Quality Management System Certificate **ISO 9001:2015**

We certify that the Quality Management System of the Organization:

MEDICA GROUP

Is in compliance with the standard UNI EN ISO 9001:2015 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. Production of filters and components for purification and filtration systems. Design and production of equipment for assembly and testing of medical devices.

Chief Operating Officer
Giampiero Belcredi

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 2 pages. The following technical datasheet provides details concerning the scope of certification.

MEDICA GROUP

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 MÉDITERRANÉE s.a.r.l. - Z.I. Menzel Jemil, lot n. 53 bis 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
direzione e coordinamento di
Kiwa Italia Holding Srl

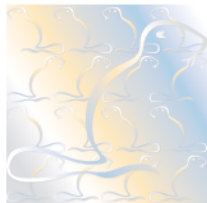
Via Cadriano, 23
40057 Granarolo dell'Emilia
(BO)

Tel +39.051.459.3.111

Fax +39.051.763.382

E-mail: info@kiwacermet.it

www.kiwa.it



Reg. Number	3686 - A	Valid From	2021-03-22
First issue date	2003-03-24	Last change date	2021-03-22
Valid Until	2024-03-23	IAF Sector	19, 14, 29

Previous expiry date

Page 2 of 2

Data sheet attached to the Certificate

ISO 9001:2015

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.
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. Production of filters for purification and filtration systems.
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. Design and production of equipment for assembly and testing of medical devices.

Chief Operating Officer
Giampiero Belcredi

Kiwa Cermet Italia S.p.A.
Società con socio unico,
soggetta all'attività di
direzione e coordinamento di
Kiwa Italia Holding Srl

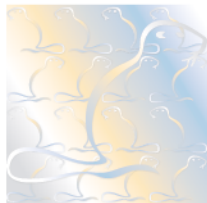
Via Cadriano, 23
40057 Granarolo dell'Emilia
(BO)

Tel +39.051.459.3.111

Fax +39.051.763.382

E-mail: info@kiwacermet.it

www.kiwa.it



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

Page 1 of 2

Quality Management System Certificate

ISO 13485:2016

We certify that the Quality Management System of the Organization:

MEDICA GROUP

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.

MEDICA GROUP

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 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
direzione e coordinamento di
Kiwa Italia Holding Srl

Via Cadriano, 23
40057 Granarolo dell'Emilia
(BO)

Tel +39.051.459.3.111

Fax +39.051.763.382

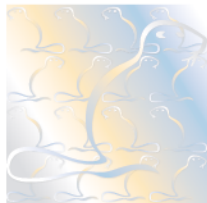
E-mail: info@kiwacermet.it

www.kiwa.it

CERMET



SGQ N° 007A



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

Page 2 of 2

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

Kiwa Cermet Italia S.p.A.
Società con socio unico,
soggetta all'attività di
direzione e coordinamento di
Kiwa Italia Holding Srl

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



Reg. Numero / Reg. Number	MED 23010A	Revisione / Revision	29
Primo rilascio / First issue date	2003-03-17	Valido da / Valid from	2018-03-16
Scadenza / Valid until	2023-03-17	Ultima modifica / Last change date	2021-05-20

Pagina / Page 1 di / of 11

Certificato CE del Sistema di Garanzia della Qualità EC Quality Assurance System Certificate

Si certifica che, sulla base dei risultati degli audit effettuati, il Sistema completo di garanzia di Qualità dell'Organizzazione/ We certify that, on the basis of the audits carried out, the full Quality Assurance System of the Organization:

MEDICA S.p.A.

Sede Legale e Operativa / Registered and Operational Headquarter:

Via degli Artigiani, 7
41036 Medolla, MO - Italia

Sede Operativa / Operational Headquarter

Medica Méditerranée Z.I. Menzel Jemil, lot n. 53 bis - Bizerte - Tunisia

è conforme ai requisiti applicabili della Direttiva 93/42/CEE e successive modifiche ed integrazioni, Allegato II escluso il pto 4, attuata in Italia con Dlgs. 46 del 1997/02/24 e successive modifiche ed integrazioni per le seguenti tipologie di Dispositivi Medici/ Is in compliance with the applicable requirements of 93/42/EEC Directive as amended, Annex II without point 4, transposed in Italy by Dlgs. 46 of 1997/02/24 as amended for the following Medical Devices:

Apparecchiatura per diagnosi di gastroenterologia
Cateteri e accessori *Catheters and accessories*
Dispositivi medici attivi di misura per urologia *Measure active medical devices for urology*
Dispositivi medici attivi diagnostico/riabilitativi per urodinamica *Diagnostic/rehabilitation active medical devices for urodynamic*
Dispositivi medici attivi diagnostico/riabilitativi per urologia e gastroenterologia ed accessori *Active Diagnostic/rehabilitation medical devices and accessories for urology and gastroenterology*
Dispositivi medici attivi per emoperfusione, plasmapheresi e reoforesi *Active medical devices for hemoperfusion, plasmapheresis, reoforesis*
Dispositivi medici attivi per trattamento sanguigno, termoregolazione e controllo fluidi *Active medical devices for blood management, thermoregulation and fluids control*
Dispositivi medici per il trattamento del sangue *Medical devices for blood treatment*
Dispositivi medici per la gestione del sangue *Medical devices for blood management*
Dispositivi medici per ultrafiltrazione *Medical devices for ultrafiltration*
Dispositivo medico attivo per perfusione d'organo *Active medical device for organ perfusion*
Dispositivo medico attivo per perfusione intraperitoneale ipertermica e perfusione di arto isolata *Active medical device for hyperthermic intraperitoneal perfusion and isolated limb perfusion*
Dispositivo per CRRT, plasmapheresi, emoperfusione, rimozione CO2 *Device for CRRT, plasmapheresis, hemoperfusion, CO2 removal*
Filtri per lavaggio/disinfezione dispositivi medici *Filters for medical devices washing/disinfection*
Linee ed accessori monouso per trattamento sanguigno *Disposable tubing sets and accessories for blood treatment*
Linee ed accessori monouso per drenaggio (toracentesi e paracentesi)
Linee ed accessori per infusione / ultrafiltrazione / recupero liquidi *Infusion / ultrafiltration / liquids recovery tubing sets and accessories*
Linee ed accessori per infusione / ultrafiltrazione / recupero liquidi / urologia per dispositivi medici attivi *Infusion / ultrafiltration / liquids recovery / urology tubing sets and accessories for active medical devices*
Linee per perfusione con ossigenatore *Perfusion lines with oxygenator*
Set nutrizione *Nutrition set*

Rif. analisi documentazione tecnica/ Ref. technical documentation analysis: del/dated 30/03/2021

Chief Operating Officer
Giampiero Belcredi

Digitally signed by:BELCREDI GIAMPIERO
Date:21/05/2021 09:45:31



Organismo Notificato n. 0476
Notified Body nr. 0476

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)
Tel +39.051.459.3.111
Fax +39.051.763.382
E-mail: info@kiwacermet.it
www.kiwacermet.it



CERTIFICATE



Reg. Numero /
Reg. Number

MED 23010A

Revisione /
Revision

29

Primo rilascio /
First issue date

2003-03-17

Valido da /
Valid from

2018-03-16

Scadenza /
Valid until

2023-03-17

Ultima modifica /
Last change date

2021-05-20

Pagina / Page 2 di / of 11

CERTIFICATE

**Allegato tecnico al Certificato/
Technical sheet enclosed to the Certificate**

Identificazione dei Dispositivi Medici/ Identification of Medical Devices:

Tipologia / Medical Devices:

Apparecchiatura per diagnosi di gastroenterologia

Classe di rischio / Risk class:

II a

Codice NANDO / NANDO codes:

MD 1301

Modello / Model:

BLU RUNNER

Tipologia / Medical Devices:

Cateteri e accessori / Catheters and accessories

Classe di rischio / Risk class:

II a

Codice NANDO / NANDO codes:

MD 0102, MDS 7006 Ethylene oxide gas sterilization (EOG)

Modello / Model:

Cateteri per manometria / Catheters for manometry

Modello / Model:

Cateteri per urodinamica / Catheters for urodynamics

Tipologia / Medical Devices:

Dispositivi medici attivi di misura per urologia / Measure active medical devices for urology

Classe di rischio / Risk class:

I m - Limitatamente agli aspetti relativi ai requisiti metrologici / restricted to the aspects concerned the metrological requirements

Codice NANDO / NANDO codes:

MD 1301

Marca / Brandname:

MENFIS DIVISION

Modello / Model:

FLOWZIG

Modello / Model:

PICOFLOW2

Chief Operating Officer

Giampiero Belcredi

Digitally signed by:BELCREDI GIAMPIERO
Date:21/05/2021 09:45:53

Kiwa Cermat 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)
Tel +39.051.459.3.111
Fax +39.051.763.382
E-mail: info@kiwacermat.it
www.kiwacermat.it

CERMET



Organismo Notificato n. 0476
Notified Body nr. 0476



Reg. Numero /
Reg. Number

MED 23010A

Revisione /
Revision

29

Primo rilascio /
First issue date

2003-03-17

Valido da /
Valid from

2018-03-16

Scadenza /
Valid until

2023-03-17

Ultima modifica /
Last change date

2021-05-20

Pagina / Page 3 di / of 11

Allegato tecnico al Certificato/ Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ Identification of Medical Devices:

Tipologia / Medical Devices:

Dispositivi medici attivi diagnostico/riabilitativi per urodinamica / *Diagnostic/rehabilitation active medical devices for urodynamic*

Classe di rischio / Risk class:

II a

Codice NANDO / NANDO codes:

MD 1301

Marca / Brandname:

MENFIS DIVISION

Modello / Model:

PICO SMART

Tipologia / Medical Devices:

Dispositivi medici attivi diagnostico/riabilitativi per urologia e gastroenterologia ed accessori / *Active Diagnostic/rehabilitation medical devices and accessories for urology and gastroenterology*

Classe di rischio / Risk class:

II a

Codice NANDO / NANDO codes:

MD 1301

Marca / Brandname:

MENFIS DIVISION

Modello / Model:

CLIPPER

Modello / Model:

DYNO SMART

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)
Tel +39.051.459.3.111
Fax +39.051.763.382
E-mail: info@kiwacermet.it
www.kiwacermet.it

Chief Operating Officer
Giampiero Belcredi

Digitally signed by:BELCREDI GIAMPIERO
Date:21/05/2021 09:46:16



Organismo Notificato n. 0476
Notified Body nr. 0476





Reg. Numero /
Reg. Number

MED 23010A

Revisione /
Revision

29

Primo rilascio /
First issue date

2003-03-17

Valido da /
Valid from

2018-03-16

Scadenza /
Valid until

2023-03-17

Ultima modifica /
Last change date

2021-05-20

Pagina / Page 4 di / of 11

Allegato tecnico al Certificato/ Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ Identification of Medical Devices:

Tipologia / Medical Devices:

Dispositivi medici attivi per emoperfusione, plasmaferesi e reoferesi / Active medical devices for hemoperfusion, plasmapheresis, reopheresis

Classe di rischio / Risk class:

II b

Codice NANDO / NANDO codes:

MD 1101

Modello / Model:

AFERSMART "F"; AFERSMART "M"; AFERSMART "T" Pentracor

Tipologia / Medical Devices:

Dispositivi medici attivi per trattamento sangue, termoregolazione e controllo fluidi / Active medical devices for blood management, thermoregulation and fluids control

Classe di rischio / Risk class:

II b

Codice NANDO / NANDO codes:

MD 1101

Modello / Model:

AcuSmart, Equasmart - Sistema per CRRT/ CRRT systems

Modello / Model:

KALOS - Dispositivo medico attivo per riscaldare o mantenere la temperatura di liquidi corporei, soluzioni per dialisi e liquidi di sostituzione / KALOS - System for heating or temperature management of body fluids, dialysis solutions and replacement fluids

Codice NANDO / NANDO codes:

MD 1101, MDS 7010

Modello / Model:

AFERSmart™, PLASMAPHER, LIPIDsmart - Sistemi per emoperfusione, plasmaferesi e reoferesi / System for hemoperfusion, plasmapheresis, reopheresis

Modello / Model:

CARDIOsmart Sistemi per trattamento dello scompenso cardiaco congestizio / System for congestive heart failure treatments

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)
Tel +39.051.459.3.111
Fax +39.051.763.382
E-mail: info@kiwacermet.it
www.kiwacermet.it

Chief Operating Officer
Giampiero Belcredi

Digitally signed by:BELCREDI GIAMPIERO
Date:21/05/2021 09:46:49



Organismo Notificato n. 0476
Notified Body nr. 0476





Reg. Numero /
Reg. Number

MED 23010A

Revisione /
Revision

29

Primo rilascio /
First issue date

2003-03-17

Valido da /
Valid from

2018-03-16

Scadenza /
Valid until

2023-03-17

Ultima modifica /
Last change date

2021-05-20

Pagina / Page 5 di / of 11

Allegato tecnico al Certificato/ Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ Identification of Medical Devices:

Tipologia / Medical Devices:

Dispositivi medici attivi per trattamento sangue, termoregolazione e controllo fluidi / Active medical devices for blood management, thermoregulation and fluids control

Modello / Model:

DECAPsmart Plus®, APHERCAP, FLOWSMART, ESTORFLOW - Sistema per emoperfusione, decapneizzazione e rimozione endotossine / System for hemoperfusion, carbon dioxide and endotoxins removal

Modello / Model:

LEUKOsmart™, LEUCAPHER - Sistema per leucocitoafesi / Leukocytapheresis System

Tipologia / Medical Devices:

Dispositivi medici per il trattamento del sangue / Medical devices for blood treatment

Classe di rischio / Risk class:

II a

Codice NANDO / NANDO codes:

MD 0102, MDS 7006 Ethylene oxide gas sterilization (EOG)

Modello / Model:

Concentratori per proteine plasmatiche ed emocomponenti / Concentrators for plasma proteins and hemocomponents

Modello / Model:

Scambiatori di calore / Heat exchangers

Tipologia / Medical Devices:

Dispositivi medici per la gestione del sangue / Medical devices for blood management

Classe di rischio / Risk class:

II b

Codice NANDO / NANDO codes:

MD 0102, MDS 7006 Radiation

Modello / Model:

Adsorbitore di leucociti / Leukocyte adsorber

Modello / Model:

Emoconcentratori / Hemoconcentrators

Chief Operating Officer
Giampiero Belcredi

Digitally signed by:BELCREDI GIAMPIERO
Date:21/05/2021 09:47:19



Organismo Notificato n. 0476
Notified Body nr. 0476

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)
Tel +39.051.459.3.111
Fax +39.051.763.382
E-mail: info@kiwacermet.it
www.kiwacermet.it

CERMET



Reg. Numero /
Reg. Number

MED 23010A

Revisione /
Revision

29

Primo rilascio /
First issue date

2003-03-17

Valido da /
Valid from

2018-03-16

Scadenza /
Valid until

2023-03-17

Ultima modifica /
Last change date

2021-05-20

Pagina / Page 6 di / of 11

Allegato tecnico al Certificato/ Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ Identification of Medical Devices:

Tipologia / Medical Devices:

Dispositivi medici per la gestione del sangue / Medical devices for blood management

Modello / Model:

Filtri per dialisi / Hemodialyzers

Modello / Model:

Linee con emoconcentratori / Tubing sets with hemoconcentrators

Modello / Model:

Plasmafrazionatori / Plasma fractionators

Codice NANDO / NANDO codes:

MD 0102, MDS 7006 Radiation, MDS 7006 Ethylene oxide gas sterilization (EOG)

Modello / Model:

Emofiltri / Hemofilters

Modello / Model:

Linee con emofiltri / Tubing sets with hemofilters

Modello / Model:

Linee con plasmafiltri / Tubing sets with plasmafilters

Modello / Model:

Plasmafiltri / Plasmafilters

Tipologia / Medical Devices:

Dispositivi medici per ultrafiltrazione / Medical devices for ultrafiltration

Classe di rischio / Risk class:

II a

Codice NANDO / NANDO codes:

MD 0102, MDS 7006 Ethylene oxide gas sterilization (EOG)

Modello / Model:

Linee con ultrafiltri / Tubing sets with ultrafilters

Modello / Model:

Ultrafiltri / Ultrafilters

Modello / Model:

Ultrafiltri per riuniti odontoiatrici / Dental chair unit ultrafilters

Chief Operating Officer

Giampiero Belcredi

Digitally signed by: BELCREDI GIAMPIERO
Date: 21/05/2021 09:47:54



Organismo Notificato n. 0476
Notified Body nr. 0476

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)
Tel +39.051.459.3.111
Fax +39.051.763.382
E-mail: info@kiwacermet.it
www.kiwacermet.it

CERMET



Reg. Numero /
Reg. Number

MED 23010A

Revisione /
Revision

29

Primo rilascio /
First issue date

2003-03-17

Valido da /
Valid from

2018-03-16

Scadenza /
Valid until

2023-03-17

Ultima modifica /
Last change date

2021-05-20

Pagina / Page 7 di / of 11

Allegato tecnico al Certificato/ Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ Identification of Medical Devices:

Tipologia / Medical Devices:

Dispositivo medico attivo per perfusione d'organo / Active medical device for organ perfusion

Classe di rischio / Risk class:

II b

Codice NANDO / NANDO codes:

MD 1101, MDS 7010

Modello / Model:

Vitasmart

Tipologia / Medical Devices:

Dispositivo medico attivo per perfusione intraperitoneale ipertermica e perfusione di arto isolata / Active medical device for hyperthermic intraperitoneal perfusion and isolated limb perfusion

Classe di rischio / Risk class:

II b

Codice NANDO / NANDO codes:

MD 1101, MDS 7010

Modello / Model:

FLEXIPER

Tipologia / Medical Devices:

Dispositivo per CRRT, plasmaferesi, emoperfusione, rimozione CO2 / Device for CRRT, plasmapheresis, hemoperfusion, CO2 removal

Classe di rischio / Risk class:

II b

Codice NANDO / NANDO codes:

MD 1101

Modello / Model:

Intensa

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)
Tel +39.051.459.3.111
Fax +39.051.763.382
E-mail: info@kiwacermet.it
www.kiwacermet.it

Chief Operating Officer
Giampiero Belcredi

Digitally signed by: BELCREDI GIAMPIERO
Date: 21/05/2021 09:48:18



Organismo Notificato n. 0476
Notified Body nr. 0476





Reg. Numero /
Reg. Number MED 23010A

Revisione /
Revision 29

Primo rilascio /
First issue date 2003-03-17

Valido da /
Valid from 2018-03-16

Scadenza /
Valid until 2023-03-17

Ultima modifica /
Last change date 2021-05-20

Pagina / Page 8 di / of 11

Allegato tecnico al Certificato/ Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ Identification of Medical Devices:

Tipologia / Medical Devices:

Filtri per lavaggio/disinfezione dispositivi medici / Filters for medical devices washing/disinfection

Classe di rischio / Risk class:

II a

Codice NANDO / NANDO codes:

MD 0108, MDS 7006 Ethylene oxide gas sterilization (EOG)

Modello / Model:

CULLIGAN PURE SSU

Modello / Model:

MEDIAPURE SSU

Tipologia / Medical Devices:

Linee ed accessori monouso per trattamento sangue / Disposable tubing sets and accessories for blood treatment

Classe di rischio / Risk class:

II a

Codice NANDO / NANDO codes:

MD 0102, MDS 7006 Ethylene oxide gas sterilization (EOG), MDS 7006 Radiation

Modello / Model:

Linee sangue / Blood tubing sets

Tipologia / Medical Devices:

Linee ed accessori monouso per drenaggio (toracentesi e paracentesi)

Classe di rischio / Risk class:

II a

Codice NANDO / NANDO codes:

MD 0102, MDS 7006 Ethylene oxide gas sterilization (EOG)

Modello / Model:

Aghi cannula / I.V. cannula needles

Modello / Model:

Set per aspirazione / Suction sets

Chief Operating Officer
Giampiero Belcredi

Digitally signed by:BELCREDI GIAMPIERO
Date:21/05/2021 09:48:38



Organismo Notificato n. 0476
Notified Body nr. 0476

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)
Tel +39.051.459.3.111
Fax +39.051.763.382
E-mail: info@kiwacermet.it
www.kiwacermet.it

CERMET

CERTIFICATE



Reg. Numero /
Reg. Number MED 23010A

Revisione /
Revision 29

Primo rilascio /
First issue date 2003-03-17

Valido da /
Valid from 2018-03-16

Scadenza /
Valid until 2023-03-17

Ultima modifica /
Last change date 2021-05-20

Pagina / Page 9 di / of 11

Allegato tecnico al Certificato/ Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ Identification of Medical Devices:

Tipologia / Medical Devices:

Linee ed accessori monouso per drenaggio (toracentesi e paracentesi)

Modello / Model:

Set per drenaggio / Drainage sets

Modello / Model:

Set per infusione / Infusion sets

Modello / Model:

Set per raccolta ultrafiltrato / Ultrafiltrate collection sets

Tipologia / Medical Devices:

Linee ed accessori per infusione / ultrafiltrazione / recupero liquidi / Infusion / ultrafiltration / liquids recovery tubing sets and accessories

Classe di rischio / Risk class:

I s - Limitatamente agli aspetti relativi al mantenimento della sterilità / restricted to the aspects concerned the maintenance of sterile conditions

Codice NANDO / NANDO codes:

MD 0102, MDS 7006 Ethylene oxide gas sterilization (EOG)

Codici / Codes:

CERTIFICATE

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)
Tel +39.051.459.3.111
Fax +39.051.763.382
E-mail: info@kiwacermet.it
www.kiwacermet.it

Chief Operating Officer
Giampiero Belcredi

Digitally signed by:BELCREDI GIAMPIERO
Date:21/05/2021 09:49:06

CERMET



Organismo Notificato n. 0476
Notified Body nr. 0476



Reg. Numero / Reg. Number	MED 23010A	Revisione / Revision	29
Primo rilascio / First issue date	2003-03-17	Valido da / Valid from	2018-03-16
Scadenza / Valid until	2023-03-17	Ultima modifica / Last change date	2021-05-20

Pagina / Page 10 di / of 11

Allegato tecnico al Certificato/ Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ Identification of Medical Devices:

Tipologia / Medical Devices:

Linee ed accessori per infusione / ultrafiltrazione / recupero liquidi / urologia per dispositivi medici attivi /
Infusion / ultrafiltration / liquids recovery / urology tubing sets and accessories for active medical devices

Classe di rischio / Risk class:

II a

Codice NANDO / NANDO codes:

MD 0102, MDS 7006 Ethylene oxide gas sterilization (EOG)

Modello / Model:

Drenaggi ureterali post-operatori / Urethral post operative drainages

Modello / Model:

Linee ed accessori per urologia / Lines and accessories for urology

Modello / Model:

Linee per esami di cavernosometria / Lines for cavernosometry

Tipologia / Medical Devices:

Linee per perfusione con ossigenatore / *Perfusion lines with oxygenator*

Classe di rischio / Risk class:

II a

Codice NANDO / NANDO codes:

MD 0102, MDS 7006 Ethylene oxide gas sterilization (EOG)

Modello / Model:

Linea unica perfusione arteria epatica - con ossigenatore O2-SMART 50AL/150AL

Modello / Model:

Linea unica perfusione rene - con ossigenatore O2-SMART 50K/150K

Modello / Model:

Linea unica perfusione vena porta - con ossigenatore O2-SMART 50PL/150PL

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)
Tel +39.051.459.3.111
Fax +39.051.763.382
E-mail: info@kiwacermet.it
www.kiwacermet.it

Chief Operating Officer
Giampiero Belcredi

Digitally signed by: BELCREDI GIAMPIERO
Date: 21/05/2021 09:49:35

CERMET



Organismo Notificato n. 0476
Notified Body nr. 0476



Reg. Numero /
Reg. Number

MED 23010A

Revisione /
Revision

29

Primo rilascio /
First issue date

2003-03-17

Valido da /
Valid from

2018-03-16

Scadenza /
Valid until

2023-03-17

Ultima modifica /
Last change date

2021-05-20

Pagina / Page 11 di / of 11

Allegato tecnico al Certificato/ Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ Identification of Medical Devices:

Tipologia / Medical Devices:

Set nutrizione / Nutrition set

Classe di rischio / Risk class:

II a

Codice NANDO / NANDO codes:

MD 0102, MDS 7006 Ethylene oxide gas sterilization (EOG)

Codici / Codes:

La lista completa dei codici, relativi ai modelli certificati, è disponibile presso Kiwa Cermet Italia./ The complete list of the codes related to the certificated models is available at Kiwa Cermet Italia. Il presente Certificato è soggetto al rispetto dei requisiti contrattuali di Kiwa Cermet Italia ed è valido solo per le tipologie di dispositivi sopra identificate soggette a sorveglianza/ This Certificate is subject to Kiwa Cermet Italia regulations and it is valid only for the above mentioned Medical Devices that are subject to survey. L'allegato tecnico è parte integrante del presente Certificato./ The technical sheet is an integrating part of this Certificate.

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)
Tel +39.051.459.3.111
Fax +39.051.763.382
E-mail: info@kiwacermet.it
www.kiwacermet.it

Chief Operating Officer
Giampiero Belcredi

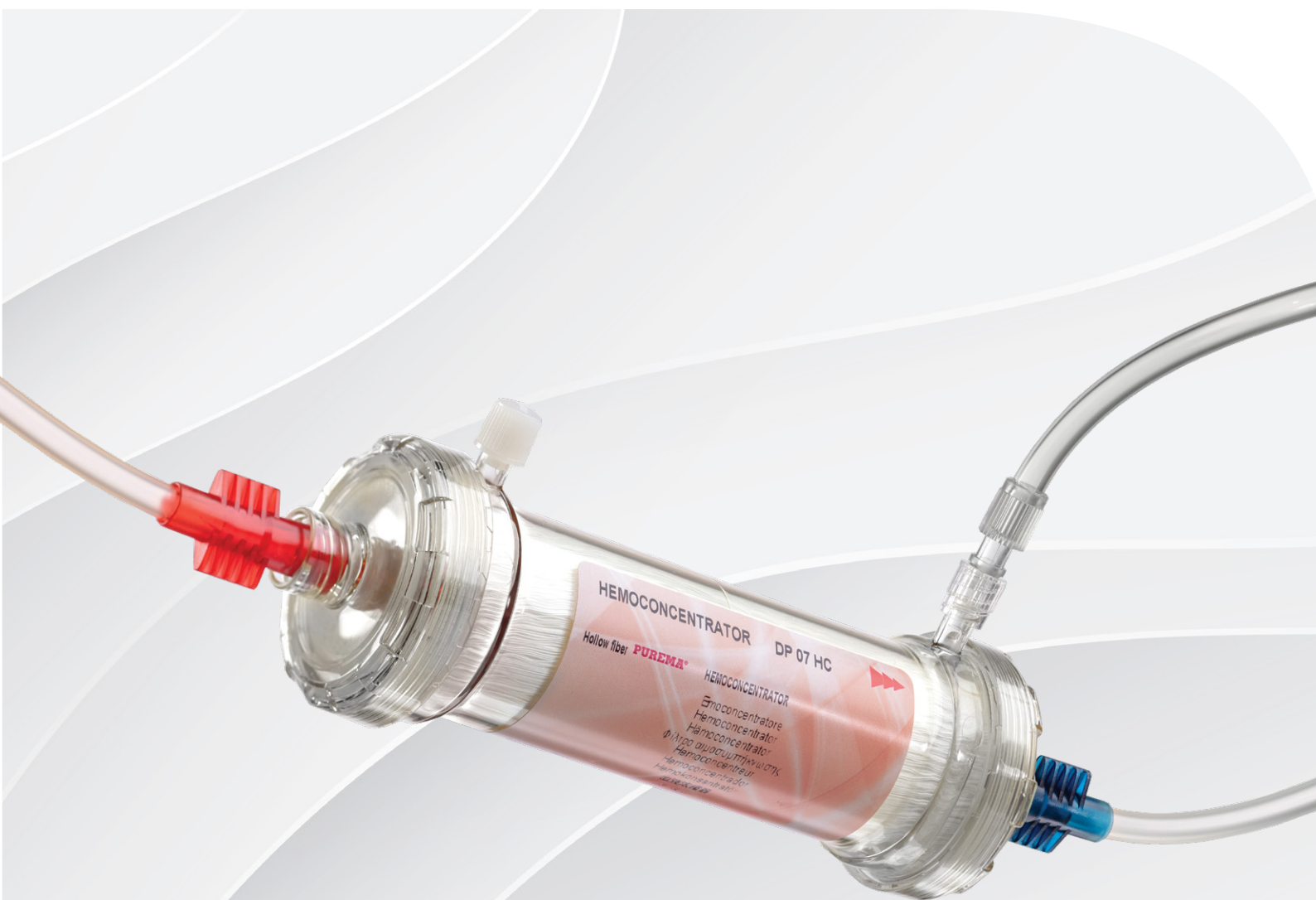
Digitally signed by:BELCREDI GIAMPIERO
Date:21/05/2021 09:50:21

CERMET



Organismo Notificato n. 0476
Notified Body nr. 0476

HEMOCONCENTRATORS



Most Complete Range of
surfaces on the market

MEDICA

Hemoconcentrators are used during cardiac surgery to control hemodilution and hematocrit levels during the surgery procedure.

Medica manufactures a complete range of hemoconcentrators based on **PUREMA®** membrane and **MediSulfone®** membrane.

The range includes models for Adult and Pediatric patients.

Medica Hemoconcentrators are available pre-rinsed to avoid the priming procedure.

PUREMA® is a registered trade mark of Membrana GmbH

MediSulfone® is a registered trade mark of MEDICA S.p.A.

PEDIATRIC HEMOCONCENTRATORS

TECHNICAL FEATURES	D050	D100	D150	DP03HC
Intended use	Neonatal	Pediatric	Pediatric	Pediatric
Hollow fiber material	MediSulfone® Polysulfone	MediSulfone® Polysulfone	MediSulfone® Polysulfone	PUREMA® Polyethersulfone
Membrane area (m2)	0,075	0,1	0,25	0,3
Fiber inner diameter (μ)	250			200
Fiber wall thickness (μ)	50			30
Priming volume (ml)	5	10	19	21
Max TMP (mmHg)	600			
Cartridge blood connectors	MLL	Tube site	Twist lock	
Cartridge filtrate connectors	FLL	Tube site	FLL	
KUF ml/h/mmHg	1.3	3.0	5.5	14
Product code - Irradiation sterile	M03665	M03985	M03098	M03967
Packaging (q.ty/box)	15	15	10	10

ADULT HEMOCONCENTRATORS

Female luer lock filtrate connection

TECHNICAL FEATURES	DP07HC	DP09HC	DP12HC	DP15HC
Intended use	Adult			
Hollow fiber material	HIGH FLUX PUREMA®			
Membrane area (m2)	0.7	0.9	1.2	1.5
Fiber internal diameter (μm)	200	200	200	200
Fiber wall thickness (μm)	30	30	30	30
Priming Blood volume (ml)	49	57	75	87
Max TMP (mmHg)	600			
Cartridge Blood Connectors	Twist Lock			
Cartridge filtrate/dialysate connectors	Female Luer Lock			
Unit Length (mm)	180	180	265	265
KUF (ml/h/mmHg)	32	41	55	63
Product code ETO sterilised	M03958	M03959	M03960	M03961
Product code sterilised by irradiation	M03968	M03969	M03970	M03971
Packaging (q.ty/box)	6			

Hansen filtrate connection

DP60HC	DP120HC	DP150HC	DP190HC	DP230HC
Adult				
HIGH FLUX PUREMA®				
0.6	1.2	1.5	1.9	2.3
200	200	200	200	200
30	30	30	30	30
39	69	87	115	133
600				
Twist Lock				
Hansen				
180	300	300	300	300
28	55	63	75	87
M03962	M03963	M03964	M03965	M03966
M03972	M03973	M03974	M03975	M03976
10	28	28	20	20

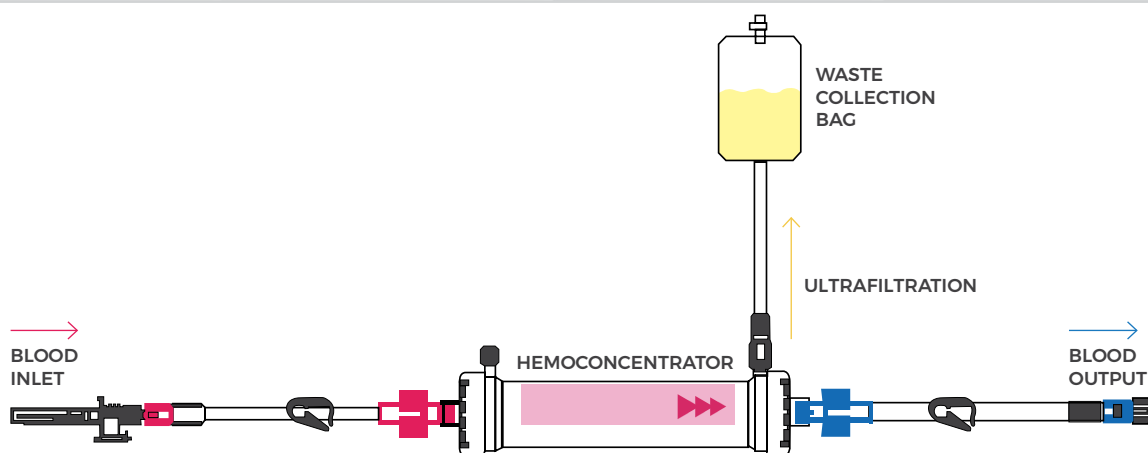
HEMOCONCENTRATOR SETS

Based on the available range of Hemoconcentrators Medica manufactures a full range of standard hemoconcentrator sets pre-assembled including the Hemoconcentrator filter both for pediatric and adult use, the sets are pre-rinsed for immediate use, furthermore Medica can manufacture on request customised hemoconcentrators sets according to specific design. Sets are sterilised by Beta Rays.

PRODUCT DESCRIPTION Neonatal and Paediatric Hemoconcentrators	Tubes length (mm)	Waste bag (ml)	CODE Rays Sterile	Q.TY (unit per case)
D 050 0.075 m2 Hemoconcentrator Set	500,500,900(uf)	500	M03738	40
D 150 0.25 m2 Hemoconcentrator Set			M03320	25
DP03HC 0.3 m2 Hemoconcentrator Set			M90006	25

PRODUCT DESCRIPTION Hemoconcentrators with female luer lock dialysate connectors	Tubes length (mm)	Waste bag (ml)	CODE Rays Sterile	Q.TY (unit per case)
DP07HC 0.7 m2 Hemoconcentrator Set	1000,1000,900(uf)	2.000	M90007	25
DP09HC 0.9 m2 Hemoconcentrator Set			M90008	25
DP12HC 1.2 m2 Hemoconcentrator Set			M90009	12
DP15HC 1.5 m2 Hemoconcentrator Set			M90010	12

PRODUCT DESCRIPTION Purema® Hemoconcentrators with Hansen dialysate connectors	Tubes length (mm)	Waste bag (ml)	CODE Rays Sterile	Q.TY (unit per case)
DP60HC 0.6 m2 Hemoconcentrator Set	1000,1000,900(uf)	2.000	M90011	25
DP120HC 1.2 m2 Hemoconcentrator Set			M90012	12
DP150HC 1.5 m2 Hemoconcentrator Set			M90013	15
DP190HC 1.9 m2 Hemoconcentrator Set			M90014	12
DP230HC 2.3 m2 Hemoconcentrator Set			M90015	12





MEDICA

MANUFACTURER

MEDICA S.p.A. Via degli Artigiani, 7
41036, Medolla (Modena) Italia
Tel: +39 0535 51159 | Fax: +39 0535 52605
Email: info@medica.it | www.medica.it



CE 0476
UNI EN ISO 9001: 2015
UNI CEI EN ISO 13485: 2016