CERTIFICATE

| | | | |
|---|---|---|---|
| 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 | | | |



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

Digitally signed by Captari Alexandru
Date: 2021.10.08 19:01:22 EEST
Reason: MoldSign Signature
Location: Moldova

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

CERTIFICATE

| | | | |
|---|---|---|---|
| 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 | | | |



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**
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Fax +39.051.763.382
E-mail: info@kiwacermet.it
www.kiwa.it

SGQ N° 007A

CERTIFICATE

| | | | |
|---|---|---|---|
| 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 | | | |



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 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.**
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Fax +39.051.763.382
E-mail: info@kiwacermet.it
www.kiwa.it

CERTIFICATE

| | | | |
|---|---|---|---|
| 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 | | | |



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**
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SGQ N° 007A

CERTIFICATE

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|---|---|---|---|
| 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 |



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, plasmaferesi e reoferesi *Active medical devices for hemoperfusion, plasmapheresis, reopheresis*
Dispositivi medici attivi per trattamento sangue, 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, plasmaferesi, 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 sangue *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

CE
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.
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www.kiwacermet.it

CERMET

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 Cermet Italia S.p.A.
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CERMET

CE
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 |



CERTIFICATE

## 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.
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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*

CERTIFICATE

## 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, dialisys 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


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CERMET

**Chief Operating Officer**
*Giampiero Belcredi*

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

CE
Organismo Notificato n. 0476
*Notified Body nr. 0476*

CERTIFICATE

## 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 leucocitoaferesi / 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


Kiwa Cermet Italia S.p.A.
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**Chief Operating Officer**
*Giampiero Belcredi*

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

CE
Organismo Notificato n. 0476
*Notified Body nr. 0476*

CERTIFICATE

## 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 ultrafiltri

**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


Kiwa Cermet Italia S.p.A.
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www.kiwacermet.it


CERMET

CE
Organismo Notificato n. 0476
*Notified Body nr. 0476*

CERTIFICATE

## 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.
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Fax +39.051.763.382
E-mail: info@kiwacermet.it
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CERMET

**Chief Operating Officer**
*Giampiero Belcredi*

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

CE

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 |



CERTIFICATE

## 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

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
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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*

CERTIFICATE

## 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:


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CERMET

Chief Operating Officer
*Giampiero Belcredi*

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Date:21/05/2021 09:49:06

CE
Organismo Notificato n. 0476
*Notified Body nr. 0476*

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 |



## 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 / Uretheral 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

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CERTIFICATE

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| Scadenza / *Valid until* | 2023-03-17 | Ultima modifica / *Last change date* | 2021-05-20 |



## 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.*

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*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.



## 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 | | | |
| Cartrige Blood Connectors | Twist Lock | | | |
| Cartrige filtrate/dialysate connectors | Female Luer Lock | | | |
| Unit Lenght (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 |

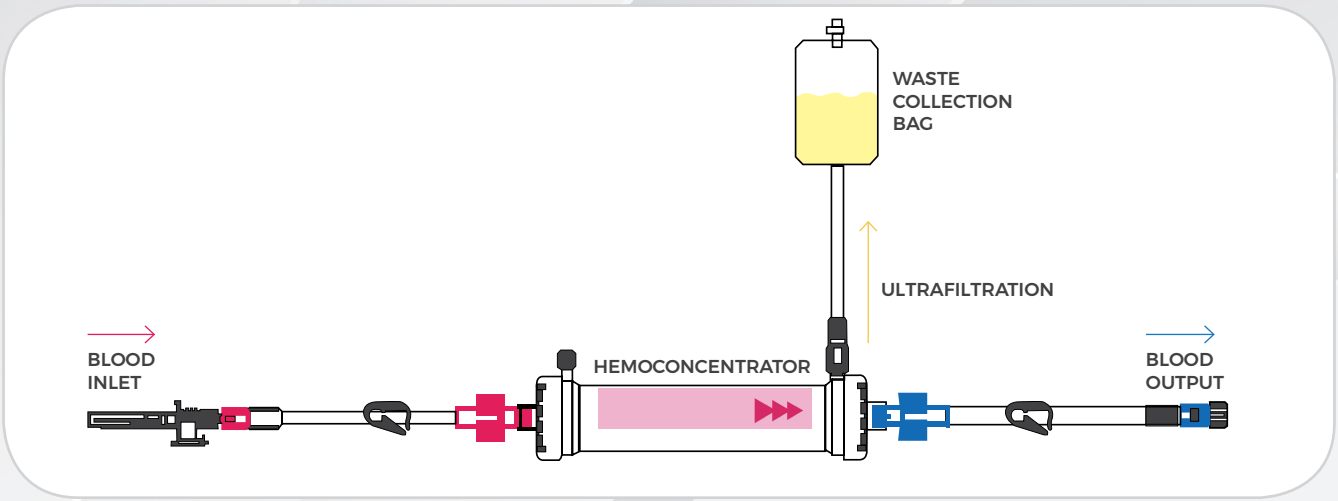
## HEMOCONCENTRATOR SETS

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 |

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