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

Digitally signed by Captari Alexandru
Date: 2023.03.15 08:42:59 EET
Reason: MoldSign Signature
Location: Moldova

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

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
Via Cadriano, 23
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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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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
Via Cadriano, 23
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www.kiwa.it

SGQ N° 007A

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

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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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.
Società con socio unico, soggetta all'attività di direzione e coordinamento di Kiwa Italia Holding S.r.l.
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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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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

Kiwa Cermet Italia S.p.A.
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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.
Società con socio unico, soggetta all'attività di direzione e coordinamento di Kiwa Italia Holding S.r.l.
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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.
Società con socio unico, soggetta
all'attività di direzione e coordinamento
di Kiwa Italia Holding S.r.l.
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E-mail: info@kiwacermet.it
www.kiwacermet.it

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.
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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 09:48:38

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:

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

Chief Operating Officer
Giampiero Belcredi

Digitally signed by:BELCREDI GIAMPIERO
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

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

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

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:*
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
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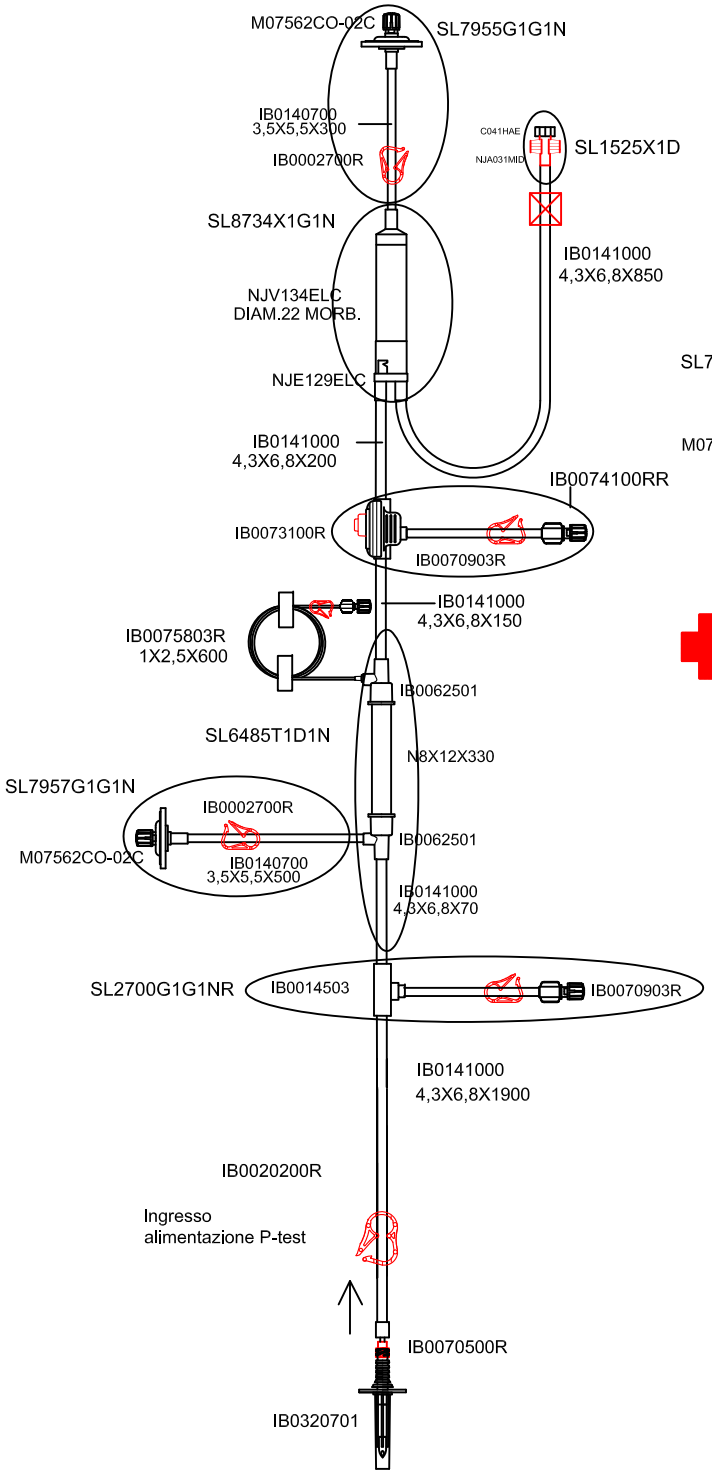
E-mail: info@kiwacermet.it
www.kiwacermet.it

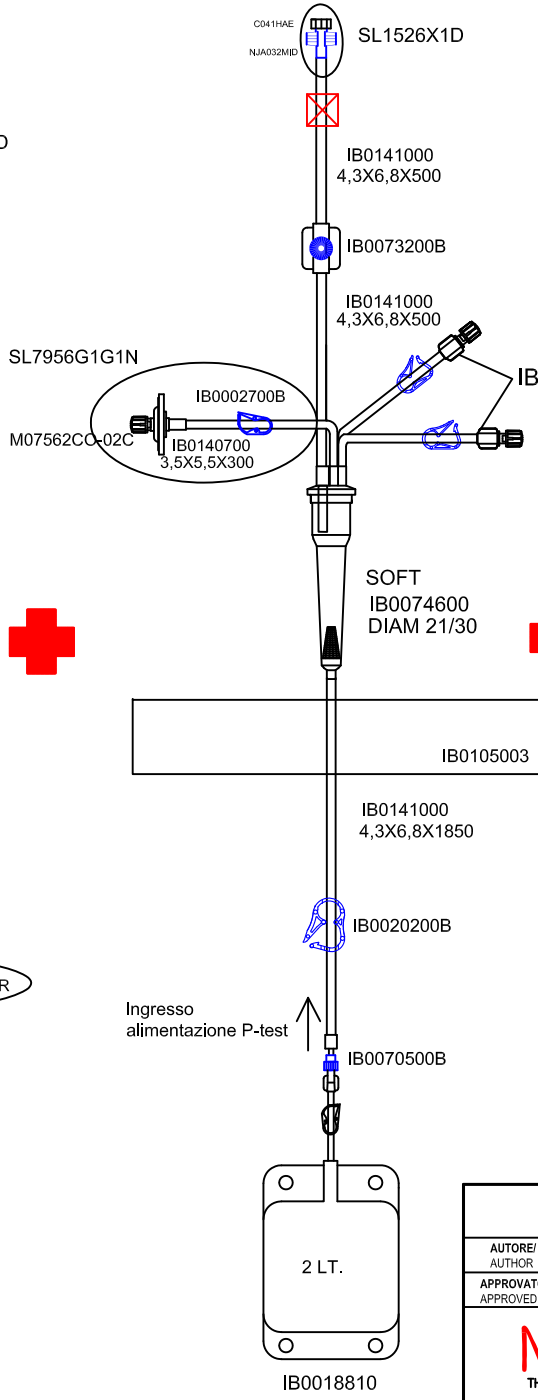
CERMET

Chief Operating Officer
Giampiero Belcredi

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

CE
Organismo Notificato n. 0476
Notified Body nr. 0476

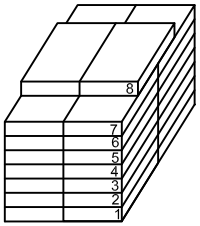


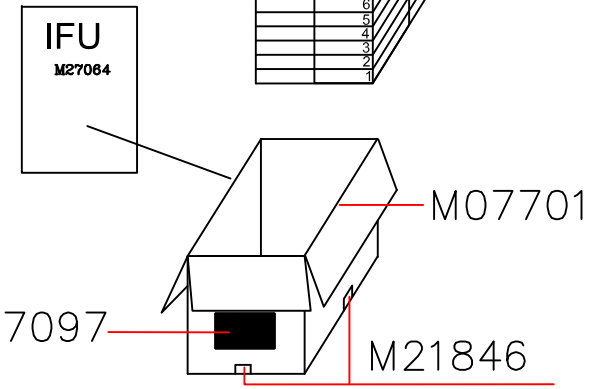


Punto da occludere prima di effetuare P-test

CONFEZIONAMENTO PRIMARIO DA UTILIZZARE	
In Medica Méditerranée	Alternativa
BUS017: Carta : M21841 Film : M21901 Inchiostro : VAR036	Codice Busta: M21933 Etich. busta : ETI014
Formato: 250X400mm	IMP : M68802

Posizionare n° 30 pezzi all'interno del cartone M07701 - 59x39x32





	NOME/ NAME	DATE/ DATA	DESCRIZIONE/ DESCRIPTION AV SET X BBRAUN DIALOG DV - ETO				
AUTORE/ AUTHOR	Ines Zarga	17/01/2022	CODICE/ CODE	REV./ REV.	STAMPO/ MOULD	COMMESSA/ DESIGN DOCUMENT	
APPROVATO DA/ APPROVED BY	Alessio Atzori	17/01/2019	M90196E	03	N/A	CDP040122A	
MEDICA			SCALA/ SCALE N/A	MATERIALE/ MATERIAL N/A	NOTE/ NOTE N/A		
THE COPYRIGHT OF THIS DRAWING IS RESERVED BY MEDICA S.p.A. PROPRIETA' RISERVATA VIETATA LA RIPRODUZIONE			STERILIZZAZIONE/ STERILIZATION ☐ N.A. ☒ ETO ☐ R ☐ _____			PAG./ SHEET 1 DI/ OF 2	

Distinta: M90196E - AV SET X BBRAUN DIALOG DV ETO

= **Fuori Validità**

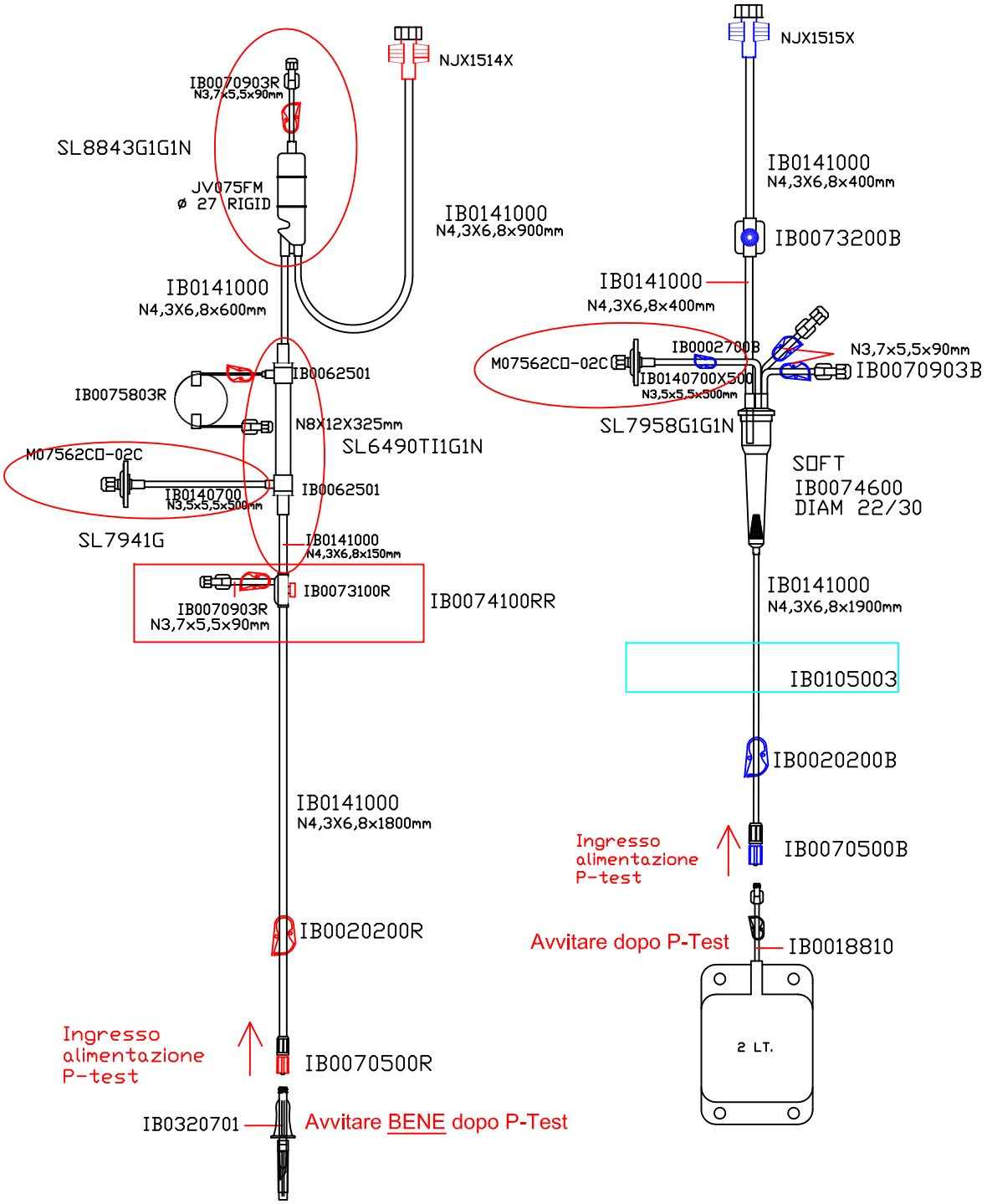
Fasi/Materiali	Descrizione	L	F	Consumo	Consumo UM Princ.	Totale	Data Inizio	Data Fine	Note del Materiale
SL7955G1G1N	SL TRASD. MEDICA LOCK/5,5 CON CLAMP ROSSO (300mm)- NO DOP	0		1,0000/NR	1,0000/NR	1,0000/NR	09-12-16		
SL8734X1G1N	-SL VASCA DIAM.22 - R - NO DOP	0		1,0000/NR	1,0000/NR	1,0000/NR	09-10-17		
IB0141000X200	SPEZZONE TUBO PVC 4.3X6.8 - 73 SH A	0		1,0000/NR	1,0000/NR	1,0000/NR	09-10-17		
IB0074100RR	SM Croce 731R+70903R	0		1,0000/NR	1,0000/NR	1,0000/NR	09-10-17		
IB0141000X150	SPEZZONE TUBO PVC 4.3X6.8 - 73 SH A	0		1,0000/NR	1,0000/NR	1,0000/NR	09-10-17		
IB0141000X850	SPEZZONE TUBO PVC 4.3X6.8 - 73 SH A	0		1,0000/NR	1,0000/NR	1,0000/NR	09-10-17		
SL1525X1D	SL ATT.DIALIZZ. ROSSO CON CAPSULA LAB. HAE	0		1,0000/NR	1,0000/NR	1,0000/NR	09-10-17		
SL6485T1D1N	SL POMPA N8X12X330+2x62501+141000x70	0		1,0000/NR	1,0000/NR	1,0000/NR	09-10-17		
IB0075803R	354 +T.1X2,5x600mm + 68226 +M07692 +27R	0		1,0000/NR	1,0000/NR	1,0000/NR	09-10-17		
SL7957G1G1N	SL TRASD. MEDICA LOCK/5,5 CON CLAMP ROSSO (500mm)- NO DOP	0		1,0000/NR	1,0000/NR	1,0000/NR	09-10-17		
SL2700G1G1NR	SL : IB0014503 + IB0070903R	0		1,0000/PZ	1,0000/PZ	1,0000/PZ	14-12-17		
IB0141000	TUBO PVC 4.3X6.8 - 73 SH A	0		1,9000/MT	0,0513/KG	0,0513/KG	09-10-17		
IB0020200R	MORSETTO modello 202 ROSSO	0		1,0000/PZ	1,0000/PZ	1,0000/PZ	09-10-17		
IB0070500R	SM Racc.LLM gir.aut. sede Ø6,8mm ROSSO - Raggi	0		1,0000/NR	1,0000/NR	1,0000/NR	09-10-17		
IB0320701	PERFORATORE 34301+ CAPS.LAB. 5	0		1,0000/NR	1,0000/NR	1,0000/NR	06-12-19		
SL1526X1D	SL ATT.DIALIZZ. BLU CON CAPSULA LAB. HAE	0		1,0000/NR	1,0000/NR	1,0000/NR	09-10-17		
IB0141000X500	SPEZZONE TUBO PVC 4.3X6.8 - 73 SH A	0		1,0000/NR	1,0000/NR	1,0000/NR	09-10-17		
IB0073200B	SM Croce sedi Ø6.8mm dritta BLU - Raggi	0		1,0000/NR	1,0000/NR	1,0000/NR	09-10-17		
IB0141000X500	SPEZZONE TUBO PVC 4.3X6.8 - 73 SH A	0		1,0000/NR	1,0000/NR	1,0000/NR	09-10-17		
IB0070903B	SM Tubo 3.7x5.5x90mm+605+27B+M07692 - Raggi	0		2,0000/NR	2,0000/NR	2,0000/NR	09-10-17		
SL7956G1G1N	SL TRASD. MEDICA LOCK/5,5 CON CLAMP BLU (300mm)- NO DOP	0		1,0000/NR	1,0000/NR	1,0000/NR	09-10-17		
IB0074600	SM Vaschetta Medica 19602+63001+199 - Raggi	0		1,0000/NR	1,0000/NR	1,0000/NR	09-10-17		
IB0141000	TUBO PVC 4.3X6.8 - 73 SH A	0		1,8500/MT	0,0500/KG	0,0500/KG	09-10-17		
IB0020200B	MORSETTO modello 202 BLU	0		1,0000/PZ	1,0000/PZ	1,0000/PZ	09-10-17		
IB0070500B	SM Racc.LLM gir.aut. sede Ø6,8mm BLU - Raggi	0		1,0000/NR	1,0000/NR	1,0000/NR	09-10-17		
IB0018810	SACCA LT.2 +70902 NON STERILE. - (OK PER RAGGI) - NO DOP	0		1,0000/NR	1,0000/NR	1,0000/NR	15-05-18		
IB0105003	FASCETTA POLIETILENE HD 175x70mm -sp.40u	0		1,0000/NR	1,0000/NR	1,0000/NR	09-10-17		
M68990	SM HDF ON LINE TAPPO	0		1,0000/NR	1,0000/NR	1,0000/NR	09-10-17		
M68220	Semil. gancio di scarico in blister	0		1,0000/PZ	1,0000/PZ	1,0000/PZ	09-10-17		
BUS017	MID-BUSTA C/PLT 25X40 STAMPATA MIDIAL	0		1,0000/NR	1,0000/NR	1,0000/NR	09-10-17		
M21933	*BUSTA NEUTRA - CARTA 60gr+FILM PET12/PE35 DIM. 25X40 CM*			1,0000/PZ	1,0000/PZ	1,0000/PZ	09-10-17		
M07277	RIBBON CERA-RESINA NERO 110mm x 360m	0		0,0003/RT	0,0003/RT	0,0003/RT	10-10-17		

= Fuori Validità

Fasi/Materiali	Descrizione	L	F	Consumo	Consumo UM Princ.	Totale	Data Inizio	Data Fine	Note del Materiale
M07701	Cartone std avana 390x590XH324 mm EST - senza logo MEDICA	0		1,0000/PZ	0,0333/PZ	0,0333/PZ	09-10-17		
M21846	ROTOLO NASTRO ADESIVO TRASPARENTE MM75x132	0		2,0000/MT	0,0005/RT	0,0005/RT	17-01-22		
M07097	ETICHETTA ADESIVA 100x150mm NEUTRA	0		1,0000/PZ	0,0333/PZ	0,0333/PZ	09-10-17		
M07277	RIBBON CERA-RESINA NERO 110mm x 360m	0		0,0004/RT	/RT	/RT	09-10-17		
M27064	Foglio istruzione linee e sacche	0		1,0000/PZ	0,0333/PZ	0,0333/PZ	09-10-17		
M21902	WOODEN PALLETS TREATED AND MARKED IN ACCORDANCE WITH ISPM 15 STANDARDS.	0		1,0000/PZ	0,0014/PZ	0,0014/PZ	09-10-17		
M21958	ANGOLARE IN CARTONE 35 X 35 X 3 H1000mm PER ALLESTIMENTO MEGAPALLET TUNISIA	0		4,0000/NR	0,0056/NR	0,0056/NR	09-10-17		
M21317	FILM ESTENSIBILE MACCHINABILE TRASP	0		0,7000/KG	0,0010/KG	0,0010/KG	09-10-17		

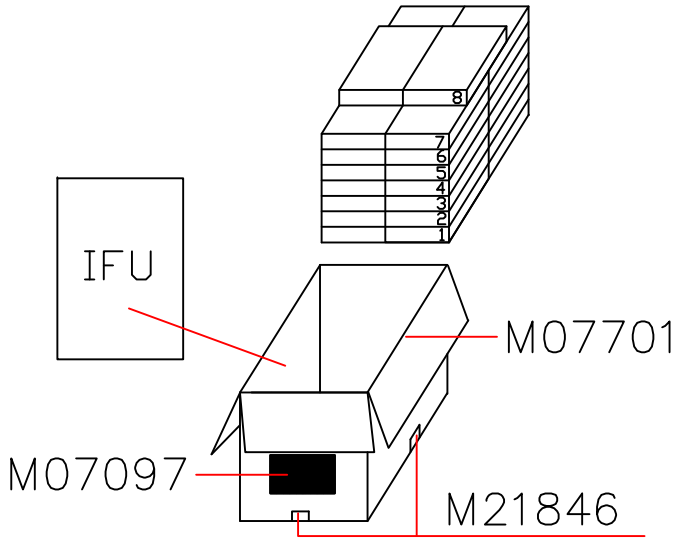
Annotazioni Padre M90196E -

N. Dis. M90196E
Rev. 03
Pag. 2 di 2
Compilato da Ines Zarga in data 17/01/2022
Approvato da Alessio Atzori in data 17/01/2022



CONFEZIONAMENTO PRIMARIO DA UTILIZZARE	
In Medica Méditerranée	Alternativa
BUS013: Carta : M21841 Film : M21901 Formato: 250X400mm	Codice Busta: M21933
Etichetta: M15028	

Posizionare n° 30 busta all'interno del cartone M07701



	NOME/ NAME	DATE/ DATA	DESCRIZIONE/ DESCRIPTION: LINEA A/V PER FRESENIUS 2008-4008				
AUTORE/ AUTHOR	Imen Bakey	13-12-2022	CODICE/ CODE	REV./ REV.	STAMPO/ MOULD	COMMESSA/ DESIGN DOCUMENT	MEDICA COPIA CONTROLLATA COPIE CONTROLEE CONTROLLED COPY
APPROVATO DA/ APPROVED BY	Alessio Atzori	13-12-2022	M90249	05	N/A	CDP020921A	
			SCALA/ SCALE: N/A	MATERIALE/ MATERIAL: N/A	NOTE/ NOTE: N/A		
			STERILIZZAZIONE/ STERILIZATION: ☐ N.A. ☐ ETO ☒ R ☐				PAG./ SHEET: 1 DI/OF 3

MEDICA

= Fuori Validità

Fasi/Materiali	Descrizione	L	F	Consumo	Consumo UM Princ.	Totale	Data Inizio	Data Fine	Note del Materiale
M21902	WOODEN PALLETS TREATED AND MARKED IN ACCORDANCE								
	WITH ISPM 15 STANDARDS.	0		1,000000/PZ	0,001666/PZ	0,001666/PZ	11-05-16		
M21317	FILM ESTENSIBILE MACCHINABILE TRASP	0		0,700000/KG	0,001166/KG	0,001166/KG	11-05-16		
M21958	ANGOLARE IN CARTONE 35 X 35 X 3 H1000mm PER								
	ALLESTIMENTO MEGAPALLET TUNISIA	0		4,000000/NR	0,006666/NR	0,006666/NR	11-05-16		

Annotazioni Padre M90249 -

N. Dis. M90249
Rev. 05
Pag. 2 di 2
in data 13-12-2022
Compilato da: Imen Bakey
Approvato da: Alessio Atzori

MEDICA

Cares for your children

A COMPLETE MULTITHERAPIES PRODUCT RANGE FOR LOW BODY WEIGHT PATIENTS

DIALYSIS

Medica's product range for low body weight patients includes a total of four dialyser models, amongst those, two sizes are high flux and two low flux. All have been developed to obtain the lowest priming volume and provide the best patient care.

LOW FLUX DIALYSER

BPA FREE

	SmartFlux LFP-06	SmartFlux LFP-03
Area m²	0,60	0,30
Inner diameter µ	200	200
Wall thickness µ	35	35
Priming volume ml	37	20
KUF ml/h/mmHg	7.5±20%	3.8±20%
MAX TMP	600 mmHg	600 mmHg
MAX blood flow rate	300 ml/min	150 ml/min
Hollow Fiber Material	PUREMA® LX	PUREMA® LX
	(Polyethersulfone)	
Sterilisation method	Irradiation	
Product code	M03689	M03986

	CLEARANCE Qb=200 ml/min; Qd=500 ml/min; Qf=0 ml/min; ±5%	CLEARANCE Qb=100 ml/min; Qd=300 ml/min; Qf=0 ml/min; ±10%
Urea (ml/min)	151	75
Creatinine (ml/min)	122	60
Phosphate (ml/min)	78	42
Vitamine B_{12} (ml/min)	30	19

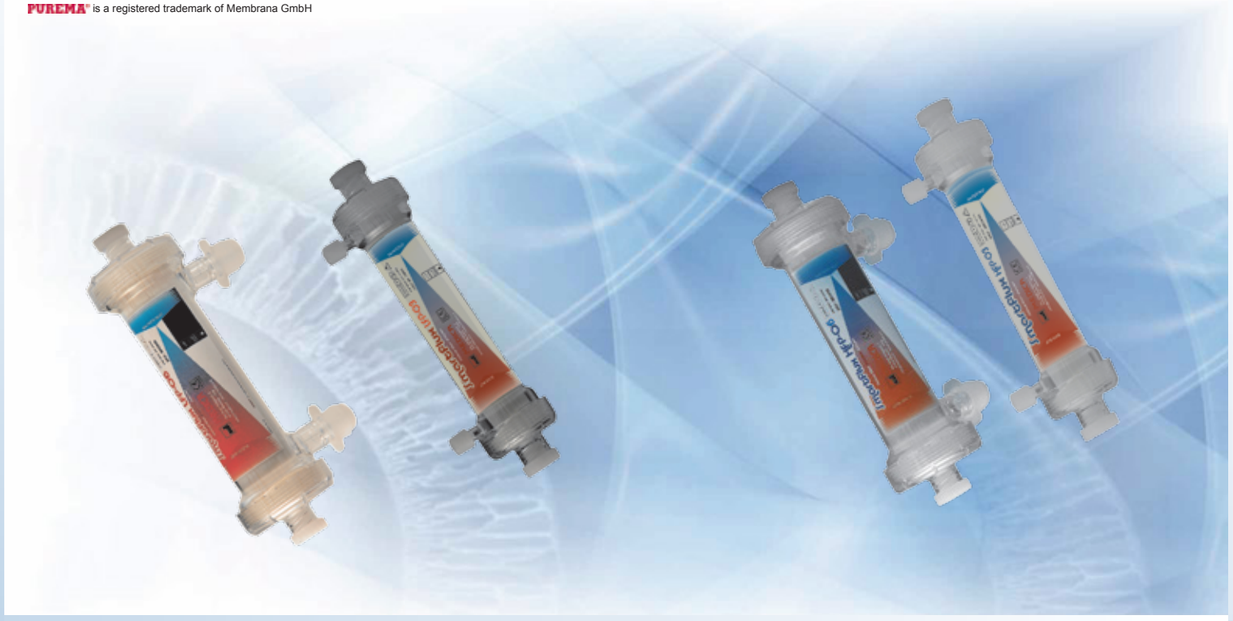
HIGH FLUX DIALYSER

BPA FREE

	SmartFlux HFP-06	SmartFlux HFP-03
Area m²	0,60	0,30
Inner diameter µ	200	200
Wall thickness µ	30	30
Priming volume ml	39	21
KUF ml/h/mmHg	30±20%	14±20%
MAX TMP	600 mmHg	600 mmHg
MAX blood flow rate	300 ml/min	150 ml/min
Hollow Fiber Material	PUREMA® H	PUREMA® H
	(Polyethersulfone)	
Sterilisation method	Irradiation	
Product code	M03690	M03987

	CLEARANCE Qb=200 ml/min; Qd=500 ml/min; Qf=0 ml/min; ±5%	CLEARANCE Qb=100 ml/min; Qd=300 ml/min; Qf=0 ml/min; ±10%
Urea (ml/min)	168	84
Creatinine (ml/min)	143	73
Phosphate (ml/min)	134	62
Vitamine B_{12} (ml/min)	86	39

PUREMA® is a registered trademark of Membrana GmbH



PLASMA EXCHANGE

To complete its current adult product range MEDICA has developed three new small size plasmafilters based on Versatile™-PES membrane.

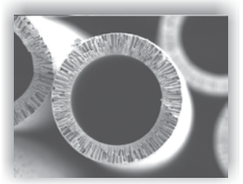
BPA FREE

PLASMART 50-100-200

	50	100	200
Area m²	0,05	0,1	0,2
Inner diameter µ	300	300	300
Wall thickness µ	85	85	85
Priming blood volume ml	3,9	8,6	13,2
Max TMP (mmHg)	100	100	100
Max blood flow (ml/min)	20	40	60
Plasma flow (ml/min)	10 to 20% of blood flow		
Cartridge blood connectors	Male Luer Lock	Twist lock	
Cartridge filtrate/dialysate connectors	Female luer lock		
Hollow Fiber Material	Versatile™-PES		
Sterilisation method	Irradiation		
Product code (Irradiation)	M03857	M03858	M03859
Sterilisation method	EtO		
Product Code (EtO)	M03863	M03864	M03865

C.R.R.T. and CARDIOSURGERY

Thanks to its innovative fiber spinning know-how, MEDICA currently offers MediSulfone® HF:



A high flux polysulfone with excellent biocompatibility characteristics, dedicated to blood filtration treatment like hemofiltration and hemoconcentration.

BPA FREE

HEMOFILTERS D050-D100-D150

MediSulfone® hemofilters have been developed to ensure the best C.R.R.T. Output.

	D050	D100	D150
Area m²	0,075	0,15	0,25
Inner diameter µ	250	250	250
Wall thickness µ	50	50	50
Priming volume ml	5	10	19
Max TMP (mmHg)	600		
Cartridge blood connectors	MLL	Tube site	Twist lock
Cartridge filtrate and dialysate connectors	FLL	Tube site	FLL
KUF ml/h/mmHg	1,3	3,0	5,5
Hollow Fiber Material	MediSulfone® Polysulfone 50,000 Daltons		
Product code (Irradiation)	M03798	M03984	M03137
Product code (EtO)	M03698	M03739	M03069

BPA FREE

HEMOCONCENTRATORS D025 -D050-D100-D150

The MEDICA "no-rinse" low priming volume hemoconcentrators can be easily inserted in the extracorporeal circuit at any time.

	D025	D050	D100	D150
Area m²	0,023	0,075	0,15	0,25
Inner diameter µ	250			
Wall thickness µ	50			
Priming volume ml	2,5	5	10	19
Max TMP (mmHg)	600			
Cartridge blood conn.	FLL	MLL	Tube site	Twist lock
Cartridge filtrate and dialysate connectors	FLL	FLL	Tube site	FLL
KUF ml/h/mmHg	0,48	1,3	3,0	5,5
Hollow Fiber Material	MediSulfone® Polysulfone 50,000 Daltons			
Sterilisation method	Irradiation			
Product code	M03956	M03662	M03985	M03098

MEDICA

Smartflux PUREMA® DIALYZERS

M27321 REV 05 CDP051118B

Distributed by

MANUFACTURER
MEDICA

MEDICA S.p.A.
Via degli Artigiani, 7
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Italia

Phone +39 0535 51159
Fax + 39 0535 52605
info@medica.it
www.medica.it

CE 0476

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

Smartflux PUREMA® DIALYZERS

MADE IN ITALY

Smartflux

HFP 130 150 170 190 210 230
HIGH FLUX PUREMA® DIALYZERS

Smartflux

LFP 120 140 160 180 200 220
LOW FLUX PUREMA® DIALYZERS

NEW

Smartflux

HFP 270
2,7m² HIGH FLUX PUREMA® DIALYZER FOR HIGH VOLUME HEMODIAFILTRATION

SMART CHOICE
experience by your side

Gruppo MEDICA Group

MEDICA Smartflux HFP | SYNTHETIC HIGH FLUX DIALYZERS

TECHNICAL SPECIFICATIONS & PERFORMANCES

Smartflux HFP eliminates middle molecular weight toxins without loss of usefull proteins.

Smartflux HFP is available in 7 different surface areas, tailored to meet patients needs.

MODEL	Smartflux HFP·130	Smartflux HFP·150	Smartflux HFP·170	Smartflux HFP·190	Smartflux HFP·210	Smartflux HFP·230	Smartflux HFP·270
Surface (m^2)	1.3	1.5	1.7	1.9	2.1	2.3	2.7
Priming Volume (ml)	75	89	101	113	123	133	156
Kuf (ml/h/mmHg)	58	63	69	75	81	87	124
Urea	194	196	197	197	198	198	199
Creatinine	185	190	193	195	196	196	197
Phosphate	178	183	185	187	189	191	193
B12 Vitamine	144	149	153	156	159	161	163
Clearance (Qb= 200 ml/min; Qd= 500 ml/min; Quf= 0)							
Urea	262	273	279	283	286	290	295
Creatinine	242	250	259	269	272	276	283
Phosphate	223	234	242	250	254	258	264
B12 Vitamine	165	176	185	195	201	205	210
Clearance (Qb= 300 ml/min; Qd= 500 ml/min; Quf= 0)							
Urea	309	321	331	339	344	348	351
Creatinine	273	285	299	310	320	327	331
Phosphate	250	262	275	283	286	291	300
B12 Vitamine	180	192	200	209	217	224	231
Clearance (Qb= 400 ml/min; Qd= 500 ml/min; Quf= 0)							
Membrane	PUREMA®						
Potting Material	Polyurethane						
Housing and Caps Material	Polycarbonate						
Sterilisation	Beta Rays						
Wall Thickness (µm)	30	30	30	30	30	30	30
Max TMP (mmHg)	600	600	600	600	600	600	600
Internal Diameter (µm)	200	200	200	200	200	200	200

HOW TO ORDER							
Product Code	M90098	M03538	M90032	M03539	M90033	M03540	M90081

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> In vitro performances according to ISO 8637:2010

MEDICA Smartflux LFP | SYNTHETIC LOW FLUX DIALYZERS

TECHNICAL SPECIFICATIONS & PERFORMANCES

Smartflux LFP offers enhanced clearance of small molecular uraemic toxins with outstanding stable clearance performance.

Smartflux LFP is available in 6 different surface areas, tailored to meet patients needs.

MODEL	Smartflux LFP·120	Smartflux LFP·140	Smartflux LFP·160	Smartflux LFP·180	Smartflux LFP·200	Smartflux LFP·220
Surface (m^2)	1.2	1.4	1.6	1.8	2,0	2.2
Priming Volume (ml)	72	82	94	106	116	127
Kuf (ml/h/mmHg)	16	18	20	23	26	29
Urea	187	190	193	195	197	198
Creatinine	178	181	184	186	190	192
Phosphate	155	161	165	170	175	180
B12 Vitamine	103	107	110	114	120	126
Clearance (Qb= 200 ml/min; Qd= 500 ml/min; Quf= 0)						
Urea	238	253	259	265	270	273
Creatinine	214	227	238	247	252	259
Phosphate	184	197	206	214	224	235
B12 Vitamine	112	117	125	131	140	145
Clearance (Qb= 300 ml/min; Qd= 500 ml/min; Quf= 0)						
Urea	283	293	301	308	319	329
Creatinine	251	263	272	286	297	304
Phosphate	199	210	222	235	252	274
B12 Vitamine	120	126	134	141	151	159
Clearance (Qb= 400 ml/min; Qd= 500 ml/min; Quf= 0)						
Membrane	PUREMA®					
Potting Material	Polyurethane					
Housing and Caps Material	Polycarbonate					
Sterilisation	Beta Rays					
Wall Thickness (µm)	35	35	35	35	35	35
Max TMP (mmHg)	600	600	600	600	600	600
Internal Diameter (µm)	200	200	200	200	200	200

HOW TO ORDER						
Product Code	M90097	M03534	M90030	M03535	M90031	M03536

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