



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

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## 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

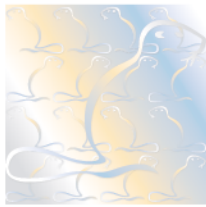
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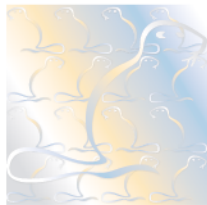
Previous expiry date

Data sheet attached to the Certificate  
**ISO 9001:2015**

<i>Operational Unit</i>	<i>Application field</i>
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

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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.

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Data sheet attached to the Certificate  
**ISO 13485:2016**

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### 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-O6	SmartFlux LFP-O3
Area m <sup>2</sup>	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	<b>PUREMA<sup>®</sup> LX</b>	<b>PUREMA<sup>®</sup> LX</b>
	(Polyethersulfone)	
Sterilisation method	Irradiation	
Product code	M03689	M03986

	<b>CLEARANCE</b> Qb=200 ml/min; Qd=500 ml/min; Qf=0 ml/min; ±5%	<b>CLEARANCE</b> 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 <sub>12</sub> (ml/min)	30	19

#### HIGH FLUX DIALYSER **BPA FREE**

	SmartFlux HFP-O6	SmartFlux HFP-O3
Area m <sup>2</sup>	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	<b>PUREMA<sup>®</sup> H</b>	<b>PUREMA<sup>®</sup> H</b>
	(Polyethersulfone)	
Sterilisation method	Irradiation	
Product code	M03690	M03987

	<b>CLEARANCE</b> Qb=200 ml/min; Qd=500 ml/min; Qf=0 ml/min; ±5%	<b>CLEARANCE</b> 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 <sub>12</sub> (ml/min)	86	39

**PUREMA<sup>®</sup>** 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<sup>™</sup>-PES** membrane.

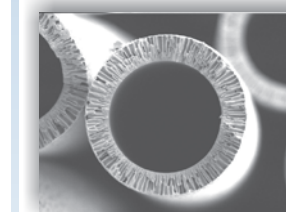
**BPA FREE**

#### PLASMART 50-100-200

	50	100	200
Area m <sup>2</sup>	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	<b>Versatile<sup>™</sup>-PES</b>		
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<sup>®</sup> 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<sup>®</sup>** hemofilters have been developed to ensure the best C.R.R.T. Output.

	D050	D100	D150
Area m <sup>2</sup>	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	<b>MediSulfone<sup>®</sup></b>		
	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 m <sup>2</sup>	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	<b>MediSulfone<sup>®</sup></b>			
	Polysulfone 50,000 Daltons			
Sterilisation method	Irradiation			
Product code	M03956	M03662	M03985	M03098

