


# DIA LX/HX DIALYZERS

**Dialife**  
SWISS QUALITY DIALYSIS 



**SUPERIOR PERFORMANCE MEETS  
UNMATCHED SAFETY**

**BPA-FREE**

 MANUFACTURED BY:  
DIALIFE SA  
Industrial Center Vedeggio 3  
Via al Fiume 3  
6807 Taverne  
Switzerland

  
0476  
UNI CEI EN ISO 13485:2016



[www.dialifegroup.com](http://www.dialifegroup.com)

# DIALYZERS DIA LX/HX

## Strong Innovation in Product Design

- Perfected fiber characteristics including better geometry, distribution and more uniform pore sizes.
- Optimized fiber packing density.
- Re-designed headers and housing, composed of polypropylene material.
- Improved polyurethane potting surface.
- Guaranteed BPA-free dialyzers, removing the risk of endocrine disruption associated to Bisphenol A.

## Tangible Technical Advantages

- Maximized fiber capillary usage.
- Increased mechanical fiber strength.
- Enhanced blood and dialysate flows.

## Value-Added Features

- Comprehensive range of surface areas.
- Removable patient label to facilitate treatment documentation.
- Convenient packaging.
- Lower weight, reducing waste and logistic costs, while having a greener environmental impact.



## Superior Results for HD Patients

- Outstanding clearance of uremic toxins and low molecular weight proteins.
- Excellent middle molecule removal.
- Preserved essential proteins like albumin.
- Superior biocompatibility.
- Lower risk of thrombogenicity.
- Ease and versatility of treatment options.
- Safer dialyzers, offering highly reliable, patient-oriented dialysis therapies.



# DIALYZERS DIA LX/HX

## Technical Data

| Dialyzer Model             | DIA 14LX | DIA 16LX | DIA 18LX | DIA 20LX | DIA 22LX | DIA 14HX | DIA 16HX | DIA 18HX | DIA 20HX | DIA 22HX |
|----------------------------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|
| Surface Area (sqm)         | 1.4      | 1.6      | 1.8      | 2.0      | 2.2      | 1.4      | 1.6      | 1.8      | 2.0      | 2.2      |
| UF Coefficient (ml/h/mmHg) | 21       | 23       | 26       | 29       | 33       | 48       | 55       | 60       | 66       | 72       |
| Priming Volume (ml)        | 85       | 98       | 110      | 125      | 137      | 87       | 100      | 109      | 120      | 138      |

### Clearances In-Vitro (ml/min)

QD = 500 ml/min - Temperature = 37°C - QF = 10 ml/min

| QB = 200 ml/min         |     |     |     |     |     |     |     |     |     |     |
|-------------------------|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|
| Urea                    | 189 | 191 | 193 | 195 | 197 | 193 | 195 | 197 | 197 | 198 |
| Creatinine              | 180 | 183 | 186 | 189 | 192 | 186 | 191 | 196 | 197 | 198 |
| Phosphate               | 179 | 185 | 190 | 192 | 195 | 182 | 188 | 192 | 195 | 196 |
| Vitamin B <sub>12</sub> | 114 | 123 | 130 | 138 | 146 | 138 | 146 | 156 | 167 | 172 |
| Inulin                  | -   | -   | -   | -   | -   | 100 | 119 | 130 | 142 | 154 |

| QB = 300 ml/min         |     |     |     |     |     |     |     |     |     |     |
|-------------------------|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|
| Urea                    | 251 | 259 | 266 | 274 | 284 | 263 | 270 | 278 | 282 | 289 |
| Creatinine              | 232 | 244 | 256 | 267 | 280 | 235 | 250 | 260 | 270 | 279 |
| Phosphate               | 228 | 240 | 250 | 260 | 272 | 239 | 255 | 269 | 281 | 288 |
| Vitamin B <sub>12</sub> | 132 | 148 | 162 | 177 | 190 | 160 | 165 | 185 | 200 | 211 |
| Inulin                  | -   | -   | -   | -   | -   | 124 | 131 | 140 | 150 | 159 |

| QB = 400 ml/min         |     |     |     |     |     |     |     |     |     |     |
|-------------------------|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|
| Urea                    | 281 | 290 | 300 | 311 | 321 | 305 | 316 | 325 | 335 | 345 |
| Creatinine              | 260 | 275 | 287 | 299 | 311 | 275 | 290 | 300 | 311 | 322 |
| Phosphate               | 267 | 280 | 292 | 305 | 317 | 309 | 315 | 334 | 340 | 352 |
| Vitamin B <sub>12</sub> | 142 | 158 | 175 | 188 | 202 | 180 | 190 | 200 | 212 | 222 |
| Inulin                  | -   | -   | -   | -   | -   | 125 | 132 | 144 | 154 | 165 |

|            |     |     |      |      |      |      |      |      |      |      |
|------------|-----|-----|------|------|------|------|------|------|------|------|
| KoA (Urea) | 836 | 945 | 1060 | 1240 | 1570 | 1010 | 1140 | 1350 | 1490 | 1830 |
|------------|-----|-----|------|------|------|------|------|------|------|------|

Performance data measured in vitro according to standard ISO 8637-1.

### Sieving Coefficients

(QB = 200 ml/min, QF = 30 ml/min)

|                  |            |
|------------------|------------|
| Inulin           | 1.0 ± 0.1  |
| β2-Microglobulin | ≥ 0.7      |
| Myoglobin        | 0.55 ± 0.1 |
| Albumin          | ≤ 0.01     |

### Materials

|                   |                  |
|-------------------|------------------|
| Membrane          | Polyethersulfone |
| Housing & Headers | Polypropylene    |
| Potting Compound  | Polyurethane     |
| Sterilization     | Irradiation      |
| Protective Caps   | Polyethylene     |



# DIA LX/HX DIALYZERS

- **OPTIMIZED DESIGN**
- **OUTSTANDING CLEARANCE LEVELS**
- **SUPERIOR BIOCOMPATIBILITY**
- **BPA-FREE MATERIAL, FOR HIGHER PATIENT SAFETY, COST SAVING AND GREENER IMPACT**
- **REDUCED RISK OF COMPLICATIONS**

**PATIENT-DRIVEN,  
QUALITY CARE.**

**Dialife**  
SWISS QUALITY DIALYSIS 



MB-F-DIA-XXL/H-XX-EN-REV.00



# AV FISTULA NEEDLES

**Dialife**  
SWISS QUALITY DIALYSIS 



**PREMIUM FISTULA NEEDLES FOR  
OPTIMAL SAFETY AND COMFORT**



## ENHANCED NEEDLE QUALITY AND FLOW PATH DESIGN. FACILITATED AND EFFECTIVE HEMODIALYSIS TREATMENT.



- Siliconized, ultra-thin needle wall and streamlined inner design to optimize blood flow and reduce resistance.
- Perfected sharpness and surface coating for a gentle puncture.
- Color-coded system to facilitate identification of gauge size and needle position.
- Enhanced back eye design to prevent lesions or blockage.
- Soft tubing with anti-bending features.
- High quality luer-lock connector with wing for secure connection to tubing set.
- Sterilization by radiation or ethylene oxide.

### AVAILABLE CONFIGURATIONS

|               |                    |
|---------------|--------------------|
| Needle Size   | 15G, 16G or 17G    |
| Needle Length | 25 mm or 32 mm     |
| Back Eye      | With or without    |
| Wing          | Fixed or rotating  |
| Clamp         | Red, blue or white |



# AV TUBING SETS

**Dialife**  
SWISS QUALITY DIALYSIS 



**ENGINEERED FOR HIGH  
QUALITY HEMODIALYSIS**



# AV TUBING SETS

**Dialife**  
SWISS QUALITY DIALYSIS

## QUALITY, SAFETY AND EASE OF USE. EXTENSIVE RANGE OF CONFIGURATIONS.



Dialife approaches every aspect of design, manufacturing and quality management of blood tubing sets with a focus on patient safety and clinician convenience.

- Superior quality, medical grade materials
- DEHP-free formulations available
- Dust removing process with static electricity
- Minimized plasticizer accumulation
- Superior mechanical stability
- Inventive product features for advanced treatment security and versatility
- Sterilization by radiation or ethylene oxide
- Availability of pediatric configurations

A large variety of tubing set models, specifications and accessories is offered, to cover the needs of every patient and be compatible with most hemodialysis systems.





# BIOCART

# Dialife

SWISS QUALITY DIALYSIS 



## SODIUM BICARBONATE CARTRIDGE FOR THE ON-LINE PRODUCTION OF BICARBONATE CONCENTRATE



## INCREASED HYGIENE AND CLEANLINESS, TO REDUCE RISK OF CONTAMINATION

Sodium bicarbonate cartridges are used for the on-line preparation of liquid bicarbonate concentrate via the hemodialysis machine. Treated water is channeled through the device under monitoring of the hemodialysis machine, to obtain a saturated bicarbonate solution.

Systems involving sodium bicarbonate cartridges represent a significant step forward for dialysis treatment, as they allow for a more hygienic supply of bicarbonate solution, hence reducing inflammations related to dialysis treatment while contributing to ultrapure dialysis.

Furthermore, the improved ergonomics of sodium bicarbonate cartridges offer additional convenience during usage and imply less storage space requirements.

Dialife offers high quality bicarbonate cartridges in the following sizes and formats:

| PRODUCT CODE    | CONTENT                                    |
|-----------------|--|
| BIOCART DLC-650 | 650 gr. NaHCO <sub>3</sub> , Ph. Eur., USP |
| BIOCART DLC-720 | 720 gr. NaHCO <sub>3</sub> , Ph. Eur., USP |
| BIOCART DLC-760 | 760 gr. NaHCO <sub>3</sub> , Ph. Eur., USP |
| BIOCART DLC-920 | 920 gr. NaHCO <sub>3</sub> , Ph. Eur., USP |



## LOWER SIZE AND WEIGHT, FOR EASIER CARRIAGE, USE AND STORAGE




# DIALUTION HD CONCENTRATE

# Dialife

SWISS QUALITY DIALYSIS 



## SODIUM BICARBONATE & ACID HEMODIALYSIS CONCENTRATE

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**BICARBONATE CONCENTRATE**



**ACID CONCENTRATE**

Bicarbonate and acid concentrates are mixed with purified water to generate dialysate solution, employed during hemodialysis treatment.

Our range of hemodialysis concentrates is European Pharmacopoeia compliant and undergoes strict production and quality control processes to ensure the highest safety and performance standards.

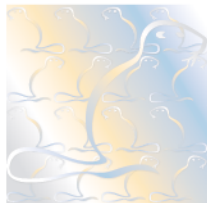
Dialife's DIALUTION solutions are offered as 5L or 10L canisters and with different formulation ranges.

With mixing ratios of 1/34 and 1/44, our acid concentrates are designed to be used with bicarbonate cartridges or liquid bicarbonate concentrate.

### ACID CONCENTRATE FORMULATION RANGE (in mmol/L)

|             |                    |
|-------------|--------------------|
| Sodium      | 138, 140           |
| Potassium   | 0, 1, 1.5, 2, 3    |
| Calcium     | 1, 1.25, 1.5, 1.75 |
| Magnesium   | 0.5, 0.75, 1       |
| Chloride    | 105.5 - 112.5      |
| Acetic Acid | 2, 3, 4, 5         |
| Bicarbonate | 32, 33, 34, 35, 36 |
| Glucose     | 0, 5.55, 11.1      |





|                  |            |                  |            |
|------------------|------------|------------------|------------|
| Reg. Number      | 7660 - M   | Valid From       | 2021-04-09 |
| First issue date | 2009-04-17 | Last change date | 2021-04-09 |
| Valid until      | 2024-04-16 |                  |            |

Quality Management System Certificate

## ISO 13485:2016

We certify that the Quality Management System of the Organization:

### DIALIFE S.A.

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

Design, production management and placing on the market of medical devices for haemodialysis.

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.

This certificate is composed of 1 page.

Kiwa Cermet Italia S.p.A.  
Società con socio unico,  
soggetta all'attività di  
direzione e coordinamento di  
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[www.kiwa.it](http://www.kiwa.it)



### DIALIFE S.A.

#### Registered Headquarters

- Via al Fiume, 3 6807 Taverne - Svizzera

#### Certified Sites

- Via al Fiume, 3 6807 Taverne - Svizzera



DUPLICATO



|                                      |            |                                       |            |
|--------------------------------------|------------|---------------------------------------|------------|
| Reg. Numero /<br>Reg. Number         | MED 28044  | Revisione /<br>Revision               | 16         |
| Primo rilascio /<br>First issue date | 2008-12-01 | Valido da /<br>Valid from             | 2018-11-30 |
| Scadenza /<br>Valid until            | 2023-12-01 | Ultima modifica /<br>Last change date | 2019-11-28 |

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## 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:

### Dialife S.A.

Sede Legale e Operativa / Registered and Operational Headquarter:

Via al Fiume, 3  
6807 Taverner - Svizzera

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:

Aghi fistula / *Fistula needles*

Cartucce e sacche di bicarbonato di sodio per emodialisi / *Hemodialysis sodium bicarbonate bags and cartridges*

Disinfettante per macchine per emodialisi / *Hemodialysis machine disinfectant*

Filtri per emodialisi (dializzatori e emodializzatori, per adulti e pediatrici) / *Filters for hemodialysis (dialyzers and hemodialyzers, for adult and pediatric)*

Monitor per dialisi / *Dialysis Machines*

Set di linee per emodialisi / *Hemodialysis tubing set*

Soluzioni concentrato A e B per emodialisi / *Hemodialysis concentrate solutions A and B*

Ultrafiltri / *Ultrafilters*

CERTIFICATE

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Rif. analisi documentazione tecnica/ Ref. technical documentation analysis: del /dated 31/5/19

Chief Operating Officer

Giampaolo Belcredi



Organismo Notificato n. 0476  
Notified Body nr. 0476

CERMET

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Reg. Numero /  
Reg. Number MED 28044

Revisione /  
Revision 16

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Valid until 2023-12-01

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Last change date 2019-11-28

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

### Identificazione dei Dispositivi Medici/ Identification of Medical Devices:

**Tipologia / Medical Devices:**  
Aghi fistula / Fistula needles

**Classe di rischio / Risk class:**  
II a

**Codice NANDO / NANDO codes:**  
MD 0102

**Marca / Brandname:**  
DIALIFE e HELBIO

**Codici / Codes:**

AXXRY25EYY; AXXRY25GY; AXXRN25EYY; AXXRN25GY; AXXFY25EYY; AXXFY25GY; AXXFN25EYY;  
AXXFN25GY; AXXRY32EYY; AXXRY32GY; AXXRN32EYY; AXXRN32GY; AXXFY32EYY; AXXFY32GY;  
AXXFN32EYY; AXXFN32GY; SXXRY25EYY; SXXRY25GY; SXXRN25EYY; SXXRN25GY; SXXFY25EYY;  
SXXFY25GY; SXXFN25EYY; SXXFN25GY SXXRY32EYY; SXXRY32GY; SXXRN32EYY; SXXRN32GY;  
SXXFY32EYY; SXXFY32GY; SXXFN32EYY; SXXFN32GY.

**Tipologia / Medical Devices:**

Cartucce e sacche di bicarbonato di sodio per emodialisi / Hemodialysis sodium bicarbonate bags and cartridges

**Classe di rischio / Risk class:**  
II b

**Codice NANDO / NANDO codes:**  
MD 0102

**Marca / Brandname:**  
DIALIFE

**Modello / Model:**

BAG

**Codici / Codes:**

BIOBAG DLB-xxx(x)

**Modello / Model:**

CARTRIDGE

**Codici / Codes:**

BIOCART DLC-xxx(x)

Chief Operating Officer

Giampiero Belcredi



Organismo Notificato n. 0476  
Notified Body nr. 0476

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

**Identificazione dei Dispositivi Medici/ Identification of Medical Devices:**

**Tipologia / Medical Devices:**

Cartucce e sacche di bicarbonato di sodio per emodialisi / *Hemodialysis sodium bicarbonate bags and cartridges*

**Marca / Brandname:**

HELBIO

**Modello / Model:**

CARTRIDGE

**Codici / Codes:**

BIOCART HBC-xxx(x)

**Modello / Model:**

BAG

**Codici / Codes:**

BIOBAG HBB-xxx(x)

**Tipologia / Medical Devices:**

Disinfettante per macchine per emodialisi / *Hemodialysis machine disinfectant*

**Classe di rischio / Risk class:**

II b

**Codice NANDO / NANDO codes:**

MD 0108

**Marca / Brandname:**

DIALIFE

**Modello / Model:**

DIA

**Codici / Codes:**

DIADISINFECT-5; DIADISINFECT-10; DIADISINFECTplus-5; DIADISINFECTplus-10

CERTIFICATE

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Chief Operating Officer  
*Giampiero Belcredi*

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

### Identificazione dei Dispositivi Medici/ Identification of Medical Devices:

#### Tipologia / Medical Devices:

Disinfettante per macchine per emodialisi / Hemodialysis machine disinfectant

#### Marca / Brandname:

HELBIO

#### Modello / Model:

BIO

#### Codici / Codes:

BIODISINFECT-5; BIODISINFECT-10; BIODISINFECTplus-5; BIODISINFECTplus-10

#### Tipologia / Medical Devices:

Filtri per emodialisi (dializzatori e emodializzatori, per adulti e pediatrici) / Filters for hemodialysis (dialyzers and hemodialyzers, for adult and pediatric)

#### Classe di rischio / Risk class:

II b

#### Codice NANDO / NANDO codes:

MD 0102

#### Marca / Brandname:

BIO-JEN

#### Codici / Codes:

BIO-JEN 12H, BIO-JEN 14H, BIO-JEN 16H, BIO-JEN 18H, BIO-JEN 20H, BIO-JEN 22H, BIO-JEN 24H.  
BIO-JEN 12L, BIO-JEN 14L, BIO-JEN 16L, BIO-JEN 18L, BIO-JEN 20L.

#### Marca / Brandname:

DIA

#### Codici / Codes:

DIA PH03, DIA PH06, DIA PL03, DIA PL06. DIA 12H-PES, DIA 14H-PES, DIA 16H-PES, DIA 18H-PES, DIA 20H-PES, DIA 22H-PES, DIA 24H-PES. DIA 12L-PES, DIA 14L-PES, DIA 16L-PES, DIA 18L-PES, DIA 20L-PES. DIA 10H, DIA 13H, DIA 14H, DIA 16H, DIA 18H, DIA 20H, DIA 22H, DIA 10L, DIA 13L, DIA 14L, DIA 16L, DIA 18L, DIA 20L, DIA 22L. DIA 14HP, DIA 16HP, DIA 18HP, DIA 20HP, DIA 22HP. DIA 14LS, DIA 16LS, DIA 18LS, DIA 20LS, DIA 22LS. DIA 10M, DIA 13M, DIA 14M, DIA 16M, DIA 18M, DIA 20M, DIA 22M. DIA 14LX; DIA 16LX; DIA 18LX; DIA 20LX; DIA 22LX; DIA 24LX; DIA 14HX; DIA 16HX; DIA 18HX; DIA 20HX; DIA 22HX; DIA 24HX

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Giampiero Belcredi



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

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#### Tipologia / Medical Devices:

Filtri per emodialisi (dializzatori e emodializzatori, per adulti e pediatrici) / Filters for hemodialysis (dialyzers and hemodialyzers, for adult and pediatric)

#### Marca / Brandname:

DIAMED

#### Codici / Codes:

DIAMED 12H, DIAMED 14H, DIAMED 16H, DIAMED 18H, DIAMED 20H, DIAMED 22H, DIAMED 24H.  
DIAMED 12L, DIAMED 14L, DIAMED 16L, DIAMED 18L, DIAMED 20L.

#### Marca / Brandname:

DIAPUR

#### Codici / Codes:

DIAPUR H14, DIAPUR H16, DIAPUR H18, DIAPUR H20, DIAPUR H22, DIAPUR L14, DIAPUR L16, DIAPUR L18, DIAPUR L20, DIAPUR L22

#### Marca / Brandname:

HELBIO

#### Codici / Codes:

BIO PH03, BIO PH06, BIO PL03, BIO PL06. BIO H1200, BIO H1500, BIO H1700, BIO H1900, BIO H2100, BIO H2300. BIO L110, BIO L140, BIO L160, BIO L180, BIO L200, BIO L220. BIO 1000H, BIO 1300H, BIO 1400H, BIO 1600H, BIO 1800H, BIO 2000H, BIO 2200H, BIO 100L, BIO 130L, BIO 140L, BIO 160L, BIO 180L, BIO 200L, BIO 220L, BIO H140P, BIO H160P, BIO H180P, BIO H200P, BIO H220P. BIO L140S, BIO L160S, BIO L180S, BIO L200S, BIO L220S. BIO 100M, BIO 130M, BIO 140M, BIO 160M, BIO 180M, BIO 200M, BIO 220M. BIO L140X; BIO L160X; BIO L180X; BIO L200X; BIO L220X; BIO L240X; BIO H140X; BIO H160X; BIO H180X; BIO H200X; BIO H220X; BIO H240X

#### Marca / Brandname:

NEPHROLIFE

#### Codici / Codes:

120HFP, 150HFP, 170HFP, 190HFP, 210HFP, 230HFP. 110LFP, 140LFP, 160LFP, 180LFP, 200LFP, 220LFP. MHP120, MHP140, MHP160, MHP180, MHP200, MHP220, MHP240. 120P, 140P, 160P, 180P, 200P.

CERTIFICATE

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|                                      |            |                                       |            |
|--------------------------------------|------------|---------------------------------------|------------|
| Reg. Numero /<br>Reg. Number         | MED 28044  | Revisione /<br>Revision               | 16         |
| Primo rilascio /<br>First issue date | 2008-12-01 | Valido da /<br>Valid from             | 2018-11-30 |
| Scadenza /<br>Valid until            | 2023-12-01 | Ultima modifica /<br>Last change date | 2019-11-28 |

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

**Identificazione dei Dispositivi Medici/ Identification of Medical Devices:**

**Tipologia / Medical Devices:**

Filtri per emodialisi (dializzatori e emodializzatori, per adulti e pediatrici) / *Filters for hemodialysis (dialyzers and hemodialyzers, for adult and pediatric)*

**Marca / Brandname:**

POLYNEXT

**Codici / Codes:**

POLYNEXT 10H, POLYNEXT 13H, POLYNEXT 14H, POLYNEXT 16H, POLYNEXT 18H, POLYNEXT 20H, POLYNEXT 22H, POLYNEXT 10L, POLYNEXT 13L, POLYNEXT 14L, POLYNEXT 16L, POLYNEXT 18L, POLYNEXT 20L, POLYNEXT 22L, POLYNEXT 10M, POLYNEXT 13M, POLYNEXT 14M, POLYNEXT 16M, POLYNEXT 18M, POLYNEXT 20M, POLYNEXT 22M. POLYNEXT 14LX; POLYNEXT 16LX; POLYNEXT 18LX; POLYNEXT 20LX; POLYNEXT 22LX; POLYNEXT 24LX; POLYNEXT 14HX; POLYNEXT 16HX; POLYNEXT 18HX; POLYNEXT 20HX; POLYNEXT 22HX; POLYNEXT 24HX.

**Marca / Brandname:**

PS

**Codici / Codes:**

PS 1000, PS 1300, PS 1400, PS 1600, PS 1800, PS 2000, PS 2200, PS 100, PS 130, PS 140, PS 160, PS 180, PS 200, PS 220, PS 100M, PS 130M, PS 140M, PS 160M, PS 180M, PS 200M, PS 220M.

**Marca / Brandname:**

VERMAFIL

**Codici / Codes:**

VERMAFIL 14LX; VERMAFIL 16LX; VERMAFIL 18LX; VERMAFIL 20LX; VERMAFIL 22LX; VERMAFIL 24LX; VERMAFIL 14HX; VERMAFIL 16HX; VERMAFIL 18HX; VERMAFIL 20HX; VERMAFIL 22HX; VERMAFIL 24HX; VERMAFIL 14HP; VERMAFIL 16HP; VERMAFIL 18HP; VERMAFIL 20HP; VERMAFIL 22HP; VERMAFIL 14LS; VERMAFIL 16LS; VERMAFIL 18LS; VERMAFIL 20LS; VERMAFIL 22LS.

CERTIFICATE

Kiwa Cermet Italia S.p.A.  
Società con socio unico, soggetta  
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di Kiwa Italia Holding S.r.l.  
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Chief Operating Officer  
*Giampiero Belcredi*



DUPLICATO \_\_\_\_\_



Reg. Numero /  
Reg. Number MED 28044

Primo rilascio /  
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Revision 16

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

**Identificazione dei Dispositivi Medici/ Identification of Medical Devices:**

**Tipologia / Medical Devices:**  
Monitor per dialisi / *Dialysis Machines*

**Classe di rischio / Risk class:**  
II b

**Codice NANDO / NANDO codes:**  
MD 1301

**Marca / Brandname:**  
DIADVANCE

**Modello / Model:**  
DIADVANCE EVOLUTION, DIADVANCE FLEX

**Marca / Brandname:**  
DIANOVA

**Modello / Model:**  
DIANOVA X2, DIANOVA X1

**Tipologia / Medical Devices:**  
Set di linee per emodialisi / *Hemodialysis tubing set*

**Classe di rischio / Risk class:**  
II a

**Codice NANDO / NANDO codes:**  
MD 0102

**Marca / Brandname:**  
DIALIFE e HELBIO

**Codici / Codes:**  
AV TUBING SET BL-XX YYY; TUBING SET HD-XX YYY

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*Giampiero Belcredi*



Organismo Notificato n. 0476  
Notified Body nr. 0476

CERMET

DUPLICATO \_\_\_\_\_



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

### Identificazione dei Dispositivi Medici/ Identification of Medical Devices:

#### Tipologia / Medical Devices:

Soluzioni concentrato A e B per emodialisi / Hemodialysis concentrate solutions A and B

#### Classe di rischio / Risk class:

II b

#### Codice NANDO / NANDO codes:

MD 0102

#### Marca / Brandname:

DIALIFE

#### Modello / Model:

DIALUTION A

#### Codici / Codes:

DIAAXXX-YYYY

#### Modello / Model:

DIALUTION B

#### Codici / Codes:

DIABXXX-YYYY

#### Marca / Brandname:

HELBIO

#### Modello / Model:

BIOLUTION A

#### Codici / Codes:

BIOAXXX-YYYY

#### Modello / Model:

BIOLUTION B

#### Codici / Codes:

BIOBXXX-YYYY

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Giampaolo Belcredi

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

**Identificazione dei Dispositivi Medici/ Identification of Medical Devices:**

**Tipologia / Medical Devices:**  
Ultrafiltri / Ultrafilters

**Classe di rischio / Risk class:**  
II a

**Codice NANDO / NANDO codes:**  
MD 0102

**Marca / Brandname:**  
ULTRADIA

**Codici / Codes:**  
ULTRADIA 210A, ULTRADIA 210B, ULTRADIA 210C, ULTRADIA 280A, ULTRADIA 280B, ULTRADIA-HDF 35,  
ULTRADIA-HDF 84.

Nota (Set di linee per emodialisi/Hemodialysis tubing set):

x(x) specifica la variante / Note: x(x) specifies the version

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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.*

CERTIFICATE

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Chief Operating Officer  
Giampiero Balardi

CE

Organismo Notificato n. 0476  
Notified Body nr. 0476

CERMET

Taverne, Switzerland, 15.02.2022

**Data Control**  
Moldova

**OFFER NR. 022204126 REV.01 Tender CAPS nr. 21049897**

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Ladies and Gentlemen,

We are pleased to send you our best offer for the following products:

**Adult Dialyzers, Blood Lines & Fistula Needles:**

Product and Price List:

**DIA LX/HX series:**

***Polyethersulfone Membrane, Polypropylene line, BPA-free, Ray Sterile, Single Use.***

***Low Flux:***

1,560 pcs - DIA 14LX (LF1.4, R Sterile): Eur 4.00

10,080 pcs - DIA 16LX (LF1.6, R Sterile): Eur 4.15

7,870 pcs - DIA 18LX (LF1.8, R Sterile): Eur 4.30

***Adult Blood Lines:***

AV Set BL-FN 002, ETO Sterile: Eur 1.55

***Fistula Needles:***

Fistula Needle (Single), ETO Sterile: Eur 0.16

Fistula Needle (Single), R Sterile: Eur 0.18

AV Fistula Needles (Pair), ETO Sterile: Eur 0.29

AV Fistula Needles (Pair), R Sterile: Eur 0.34

Minimum Ordering Quantity: 1 full container, quantities as follows:

| Container Loading | Dialyzers (DIA LX) Only | DIA + Tubing Sets (TS) | DIA +TS + AV Pairs Fistula Needles (AVF) |
|-------------------|-------------------------|------------------------|--|
| Container 20GP    | 13,608 DIA              | 6,576 DIA + 6,576 TS   | 6,288 DIA + 6,288 TS + 6,300 AVF         |
| Container 40GP    | 28,560 DIA              | 13,776 DIA + 13,776 TS | 13,032 DIA + 13,032 TS + 13,300 AVF      |
| Container 40HQ    | 31,680 DIA              | 15,552 DIA + 15,552 TS | 14,640 DIA + 14,640 TS + 14,700 AVF      |

Delivery Term:

For DIA LX dialyzers, Fistula needles and Blood lines:  
FOB China Seaport

PS: kindly note that only full container orders can be processed.



**Bicarbonate Cartridges:**Product and Price List:

BIOCART DLC-760 (760gr): Eur 1.65

Minimum Ordering Quantity: 1 full container 40GP, quantities as follows:

1 container 40GP = 21,000 cartridges or 23,552 bags

Delivery Term: FOB Mersin, Turkey

PS: kindly note that only full container orders can be processed. Should products be ordered/shipped according to quantities which are lower than 1 full container, prices will remain the same but expressed on EXW Factory basis.

**Bicarbonate and Acid Concentrates:**Product and Price List:

HEMODIALYSIS BICARBONATE CONCENTRATE 5L: Eur 2.40

HEMODIALYSIS BICARBONATE CONCENTRATE 10L: Eur 3.80

ACID CONCENTRATE in 5L canister: Without glucose: EUR 2.60 / With glucose: EUR 2.70

ACID CONCENTRATE in 10L canister: Without glucose: EUR 4.20 / With glucose: EUR 4.35

Minimum Ordering Quantity: 1 full container 40GP, quantities as follows:

3,150 acid/bicarb. concentrate 5L or 2,100 acid/bicarb. concentrate 10L

Delivery Term: FOB Mersin, Turkey

PS: kindly note that only full container orders can be processed. Should products be ordered/shipped according to quantities which are lower than 1 full container, prices will remain the same but expressed on EXW Factory basis.

**Other Terms & Conditions Applicable For All Products Herein Offered:**

Territory: Moldova. Tender CAPS nr. 21049897

Delivery time: Each order ready for dispatch within 8 weeks (+/- 2 weeks).

Minimum Yearly volumes: According to tender quantities.

Payment terms: Cash in advance, OR  
Irrevocable and confirmed letter of credit, payment at sight, partial shipments allowed, confirmation cost at Applicant's charge.

Offer validity: 30 days

Hoping that our proposal will meet your requirements, we remain at your disposal for any clarification.

Best regards,

**DIALIFE SA**

Prepared by:  
Name: Pablo Dosil Rosende

Approved by:  
Name: Franck Tinti

