

## DECLARATION OF CONFORMITY

We, Inspramed Medikal Sanayi ve Ticaret Anonim Şirketi, located at “Serbest Bölge, 8.Cad., No:29, 38070 Melikgazi,Kayseri/TURKEY”, here with declare under our sole responsibility conformity of the below mentioned medical products meet all the provision of the 93/42/EEC Medical Device Directive for EC Compliance and related harmonized standards.

Medical Device Name : **Insprazol Haemodialysis Acid Concentrate**  
Related Directives and Annex : MDD 93/42/EEC Medical Device Directive – Annex II (excluding Section 4)  
Rule : 3  
Class : IIb – Non Sterile Product  
GMDN Code : 35849  
CE Certificate Number : M.2013.106.2211  
Notified Body Number : 2292  
Initial Assessment Date : 13.07.2013  
Registration Date : 25.07.2013  
Reissue Date/No : 11.08.2018/01  
Expiry Date : 30.08.2023

Medical Device Name : **Insprazol Haemodialysis Basic Concentrate**  
Related Directives and Annex : MDD 93/42/EEC Medical Device Directive – Annex II (excluding Section 4)  
Rule : 3  
Class : IIb – Non Sterile Product  
GMDN Code : 35849  
CE Certificate Number : M.2013.106.2211  
Notified Body Number : 2292  
Initial Assessment Date : 13.07.2013  
Registration Date : 25.07.2013  
Reissue Date/No : 11.08.2018/01  
Expiry Date : 30.08.2023

Medical Device Name : **Inspracart Haemodialysis Sodium Bicarbonate Cartridge**  
Related Directives and Annex : MDD 93/42/EEC Medical Device Directive – Annex II (excluding Section 4)  
Rule : 3  
Class : IIb – Non Sterile Product  
GMDN Code : 35849  
CE Certificate Number : M.2013.106.2211  
Notified Body Number : 2292  
Initial Assessment Date : 13.07.2013  
Registration Date : 25.07.2013  
Reissue Date/No : 11.08.2018/01  
Expiry Date : 30.08.2023

Medical Device Name : **Insprabag Haemodialysis Sodium Bicarbonate Bag**  
Related Directives and Annex : MDD 93/42/EEC Medical Device Directive – Annex II (excluding Section 4)

## DECLARATION OF CONFORMITY

Rule : 3  
 Class : IIb – Non Sterile Product  
 GMDN Code : 35849  
 CE Certificate Number : M.2013.106.2211  
 Notified Body Number : 2292  
 Initial Assessment Date : 13.07.2013  
 Registration Date : 25.07.2013  
 Reissue Date/No : 11.08.2018/01  
 Expiry Date : 30.08.2023

Medical Device Name : **Inspradez Haemodialysis Machine Disinfectant**  
 Related Directives and Annex : MDD 93/42/EEC Medical Device Directive –  
 Annex II (excluding Section 4)

Rule : 15  
 Class : IIb – Non Sterile Product  
 GMDN Code : 47631  
 CE Certificate Number : M.2013.106.2211  
 Notified Body Number : 2292  
 Initial Assessment Date : 13.07.2013  
 Registration Date : 25.07.2013  
 Reissue Date/No : 11.08.2018/01  
 Expiry Date : 30.08.2023

### Product Models

- **INSPRASOL**

| NO | PRODUCT CODE     | FORMULATION | PACKAGING AMOUNTS |
|----|------------------|-------------|-------------------|
| 1  | INSPRASOL A 1XXX | SPECIFIC    | 3,78 Liters       |
| 2  | INSPRASOL A 1XXX | SPECIFIC    | 5 Liters          |
| 3  | INSPRASOL A 1XXX | SPECIFIC    | 7,8 Liters        |
| 3  | INSPRASOL A 1XXX | SPECIFIC    | 8 Liters          |
| 4  | INSPRASOL A 1XXX | SPECIFIC    | 10 Liters         |
| 5  | INSPRASOL A 1XXX | SPECIFIC    | 1000 Liters       |

| PRODUCT CODE  | FORMULATION | PACKAGING AMOUNTS |
|---------------|-------------|-------------------|
| INSPRASOL B35 | SPECIFIC    | 5 Liters          |
| INSPRASOL B35 | SPECIFIC    | 6 Liters          |
| INSPRASOL B35 | SPECIFIC    | 10 Liters         |

## DECLARATION OF CONFORMITY

- **INSPRACART**

| <b>PRODUCT NAME</b> | <b>SODIUM BICARBONATE (Grams)</b> |
|---------------------|-----------------------------------|
| INSPRACART          | 550                               |
| INSPRACART          | 650                               |
| INSPRACART          | 720                               |
| INSPRACART          | 750                               |
| INSPRACART          | 760                               |
| INSPRACART          | 850                               |
| INSPRACART          | 920                               |
| INSPRACART          | 960                               |

- **INSPRABAG**

| <b>PRODUCT NAME</b> | <b>SODIUM BICARBONATE (Grams)</b> |
|---------------------|-----------------------------------|
| INSPRABAG           | 650                               |
| INSPRABAG           | 840                               |
| INSPRABAG           | 900                               |
| INSPRABAG           | 5000 (5 kgs)                      |
| INSPRABAG           | 8400 (8,40 kgs)                   |
| INSPRABAG           | 25000 (25 kgs)                    |

- **INSPRADEZ**

| <b>PRODUCT CODE</b>  | <b>FORMULATION</b> | <b>PACKAGING AMOUNTS</b> |
|----------------------|--------------------|--------------------------|
| INSPRADEZ C 50       | SPECIFIC           | 5 Liters                 |
| INSPRADEZ C 50       | SPECIFIC           | 10 Liters                |
| INSPRADEZ C.M.L. 2,5 | SPECIFIC           | 5 Liters                 |
| INSPRADEZ C.M.L. 2,5 | SPECIFIC           | 10 Liters                |

## DECLARATION OF CONFORMITY

### Manufacturer

**Name** : Inspramed Medikal Sanayi Ve Ticaret Anonim Şirketi  
**Address** : Serbest Bölge 8. Cadde No: 29, 38070 Melikgazi, Kayseri / TÜRKİYE  
**Phone** : +90 352 311 4210  
**Fax** : +90 352 311 4220  
**E-mail** : commercial@inspramed.com.tr  
**Website** : www.inspramed.com.tr

### Authorized Representative (EU Representative)

**Name** : MA Medical BV  
**Address** : De Vork 8, 3984 PA Odijk, Netherlands  
**Phone** : +31 30 889 3010  
**E-mail** : ton@mamedical.nl

### Notified Body

**Name** : Udem International Certification Auditing Training Centre Industry and Trade Co. Ltd.  
**Address** : Mutlukent Mah. 2073 Sk. No:10 Ümitköy - Çankaya / Ankara  
**Phone** : +90 312 443 0390  
**Fax** : +90 312 441 0376  
**Website** : www.udem.com.tr

Applied harmonized standards are specified following.

- MDD 93/42/EEC Annex II
- MDR (UA) 2017/745
- European Pharmacopeia 10
- EN ISO 13485: 2016 Quality Management System Medical Devices
- EN ISO 14971: 2019 Application of risk management to medical devices
- EN ISO 20417:2021 Medical devices - Information to be supplied by the manufacturer
- EN 10993-1:2020 Biological evaluation of medical devices.
- MDCG 2020-3 Guidance on significant changes
- MDCG 2021-6 Regulation (EU) 2017/745 – Questions & Answers regarding clinical investigation
- MDCG 2020-13 Clinical evaluation assessment report template
- MDCG 2020-10/2 Guidance on safety reporting in clinical investigations
- MDCG 2020-8 Guidance on PMCF evaluation report
- MDCG 2020-7 Guidance on PMCF plan
- MDCG 2020-5 Guidance on clinical evaluation – Equivalence
- MDCG 2019-9 - Rev.1 Summary of safety and clinical performance
- MDCG 2020-1 Guidance on clinical evaluation
- MEDDEV 2.4/1 rev. 9 Classification of medical devices
- MEDDEV 2.7/1 rev. 4 Clinical evaluation
- EN 15223: 2021-1 Medical devices- Symbols to be used with medical device labels, labelling and information to be supplied
- EN ISO 23500-3:2019 Water for haemodialysis and related therapies
- EN ISO 23500-4:2019 Concentrates for haemodialysis and related therapies
- EN ISO 23500-5:2019 Quality of dialysis fluid for haemodialysis and related therapies
- EN ISO 11737-1 Sterilization of healthcare products- Microbiological methods- Part 1 : Determination of a population of microorganisms on products
- TS EN ISO 13624:2021 Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity in the medical area - Test method and requirements (phase 2, step 1)
- TS EN 13727+A2:2015 Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of bactericidal activity in the medical area - Test method and requirements (phase 2, step 1)
- TS-EN 14347:2006 Chemical disinfectants and antiseptics - Basic sporicidal activity - Test method and requirements (phase 1, step 1)

## DECLARATION OF CONFORMITY

- TS EN 14348:2005 Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of mycobactericidal activity of chemical disinfectants in the medical area including instrument disinfectants - Test methods and requirements (phase 2, step 1)
- TS EN 14476+A1:2019 TS EN 14476+A1:2019 Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of virucidal activity in the medical area - Test method and requirements (Phase 2/Step 1)
- TS EN 14561:2006 Chemical disinfectants and antiseptics - Quantitative carrier test for the evaluation of bactericidal activity for instruments used in the medical area - Test method and requirements (phase 2, step 2)
- TS EN 14562:2006 Chemical disinfectants and antiseptics - Quantitative carrier test for the evaluation of fungicidal or yeasticidal activity for instruments used in the medical area - Test method and requirements (phase 2, step 2)
- TS EN 14563 : 2010 Chemical disinfectants and antiseptics - Quantitative carrier test for the evaluation of mycobactericidal or tuberculocidal activity of chemical disinfectants used for instruments in the medical area - Test method and requirements (phase 2, step 2)
- TS EN 12353:2021 Chemical disinfectants and antiseptics - Preservation of test organisms used for the determination of bactericidal (including Legionella), mycobactericidal, sporicidal, fungicidal and virucidal (including bacteriophages) activity

The manufacturer accepted full responsibility for the production conformity to the requirements stated in the declaration.

**Approved By** : Necaatdin Tekin  
**Position** : Director







# E C C E R T I F I C A T E

## Full Quality Assurance System Medical Devices Directive 93/42/EEC Annex II

Company Name : İnspiramed Medikal Sanayi ve Ticaret A.Ş.

Company Address : Serbest Bölge 8. Cad. No:29 38070 Melikgazi KAYSERİ / TÜRKİYE

Related Directives and Annex : MDD 93/42/EEC Medical Devices Directive - Annex II  
(Excluding Section 4)

Product : Class IIb - Non-Sterile Product  
- Haemodialysis Machine Disinfectant  
- Haemodialysis Acidic and Basic Concentrates  
- Haemodialysis Sodium Bicarbonate Cartridge  
- Haemodialysis Sodium Bicarbonate Bag

GMDN : 35849, 47631

Certificate Number : M.2013.106.2211  
Report Number : UD.1665.YB  
Initial Assessment Date : 13.07.2013  
Registration Date : 25.07.2013  
Recertification Assessment Date : 11.05.2018  
Reissue Date : 31.08.2018/01  
Revision Date /No : -  
Expiry Date : 30.08.2023

  
UDEM International Certification  
Auditing Training Centre Industry  
and Trade Inc. Co.

UDEM hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance audits, defined by Annex II, section 5 of the forementioned directive. According to Annex II, section 4 an EC design- examination certificate is required for placing the Class III devices on the market. This certificate remains as the property of UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co. to whom it must be returned upon request. The above named company and UDEM must keep a copy of this certificate for 5 years from the registration of the certificate. Usage of the CE mark is under the responsibility of the manufacturer with the completion of EC Declaration of Conformity. The above mentioned company must notify all changes related with the approved product to UDEM. If UDEM will not renew the expiry date of this certificate in question, the mentioned company should stop placing the product on the market. The currency of the certificate can be checked through [www.udem.com.tr](http://www.udem.com.tr).

CE  
2292



Address: Mutlukent Mahallesi 2073 Sokak (Eski 93 Sokak) No:10 Çankaya – Ankara – TURKEY  
Phone: +90 312 443 03 77 Fax: +90 312 441 87 72  
E-mail: [info@udemtd.com.tr](mailto:info@udemtd.com.tr) [www.udem.com.tr](http://www.udem.com.tr)





# Certificate

**ISO 13485 : 2016**

**INSPRAMED MEDİKAL SANAYİ  
VE TİCARET A.Ş.**

Anbar Sb Mah. 8. Cad. No: 29 Melikgazi/ Kayseri/ TURKEY

*This certificate shows that the medical devices - quality management system (EN ISO 13485:2016) of the above company was approved by PCA Certification for the following scope, the validity of the certificate depends on the company's pass the annual surveillance audits and company's maintenance the related management system conditions according to international accreditation criteria*

## SCOPE

*Manufacturing and sales of hemodialysis, acidic and basic concentrates, hemodialysis sodium bicarbonate cartridge, hemodialysis sodium bicarbonate bag, hemodialysis machine disinfectants*

## GROUP CODE

A

|                           |  |
|---------------------------|--|
| <b>Certificate No</b>     | : TC-75108   |
| <b>Registration Date</b>  | : 01.03.2019                                       |
| <b>Reissue Date</b>       | : 17.02.2023                                       |
| <b>Expiry Date</b>        | : 28.02.2024                                       |
| <b>Certificate Period</b> | : 3 Years (From the date of registration)          |
| <b>Exclusion</b>          | : 7.5.3 / 7.5.4 / 7.5.5 / 7.5.7 / 7.5.9.2 / 7.5.10 |



PCA Certification Approval

PCA Sertifikasyon Hizmetleri Limited Şirketi  
Orta Mah. Ordu Şk. İşpark C Blok No:26/23 Kartal/İSTANBUL  
Tel: +90 216 510 63 48-49 Pbx Faks: +90 216 517 63 49  
www.pca-tr.com info@pca-tr.com

FR.86 Rev.4



**INSPRAMED**

A D.med Group Company

# PRODUCT CATALOG

## HAEMODIALYSIS CONSUMABLES





## ABOUT US:

Inspramed Medical is an international medical company that produces haemodialysis consumables.

It was founded in 2013 and has since established itself as a quality-focused manufacturer of haemodialysis acid and basic concentrates, sodium bicarbonate cartridges / bags and haemodialysis machine disinfectants.

Thanks to its highly motivated staff and excellent global partners, Inspramed Medical has become a reputed manufacturer in the dialysis field with all its products well-established in different countries.

Inspramed commits to providing high-quality and cost-efficient products through a reliable delivery service to the haemodialysis community around the world.

In January 2021, Inspramed Medical was acquired by D.med Healthcare Group.

### **About D.med Healthcare Group:**

*Headquartered in Düsseldorf, Germany, D.med Healthcare Group operates globally through a network of premises in over 20 countries as a provider of medical services and products with a focus on renal care, diabetes, and other fields of internal medicine.*

*For more information on D.med, please visit: [www.dmed-healthcare.com](http://www.dmed-healthcare.com)*

*For more information on Inspramed, please visit: [www.inspramed.com.tr](http://www.inspramed.com.tr)*



# QUALITY POLICY

To meet the needs and expectations today and in the future, we make our clients our focus.

With the principle “the quality of our products and services starts with the quality of our employees”, we engage in motivating our team to develop a passion for excellence.

Our activities are based on the 42/93/EEC Medical Device Directive and EN ISO:13485 2016 standard and quality management system and we ensure compliance with these regulations with our high quality-minded approach to our business that will also help us in the future application of the 745/2017 Medical Device Regulation (MDR).

We aim to be a leading company in our field, building our position by continuously improving our processes and striving to be an inspiring example to other organizations.



European Conformity Standards (CE)



International Organization for Standardization (ISO 13485:2016)



Free Sales Certificate (FSC)

# OUR PRODUCT RANGE

## Insprazol Haemodialysis Acid Concentrates



## Insprazol Haemodialysis Basic Concentrates



## Inspradez Haemodialysis Machine Disinfectants



## Inspracart Haemodialysis Sodium Bicarbonate Cartridges



## Insprabag Haemodialysis Sodium Bicarbonate Bags





## OUR PRODUCTS | ACID CONCENTRATES

### INSPRASOL CANISTERS

- Used for treatment of patients with acute or chronic renal failure.
- Used by diluting an appropriate amount of Insprasol Haemodialysis Basic Concentrate with purified water.
- Different formulations should be chosen according to the requirements of the patient's treatment as determined by a nephrologist.
- Instructions for use should be taken into consideration during the application.
- Should be kept closed in its original packaging.
- Available in 5,8 and 10-liter HDPE canisters.
- Shelf life: 36 months (according to stability test reports).



### INSPRASOL IBC TANK

- Mostly used by haemodialysis centres / hospitals, which have a large number of treatment places and usually have a central acid supply system with ring line installed.
- Available as 1000-liter IBC tanks.



### INSPRASOL POWDER

- Ingredients should be mixed by diluting purified water. The instructions and product information of the manufacturer should be carefully considered.
- Includes all necessary materials to obtain 100 liters of liquid haemodialysis acidic concentrate.
- Usually formed by 7 parts [Sodium chloride (NaCl), Calcium chloride ( $\text{CaCl}_2$ ), Magnesium chloride, ( $\text{MgCl}_2$ ), Potassium chloride (KCl), Glucose ( $\text{C}_6\text{H}_{12}\text{O}_6$ ), Acetic Acid ( $\text{CH}_3\text{COOH}$ ) and Sodium Acetate ( $\text{NaCH}_3\text{COO}$ )].
- The exact mix of ingredients must be defined based on specific treatment requirements.
- All Insprasol liquid acidic concentrate formulations are also available for Insprasol Haemodialysis Powder Acid Concentrate.



## OUR PRODUCTS | ACID CONCENTRATES

### Insprazol Haemodialysis Acid Concentrates Formulation List

#### 1+34

| Product Name / Code | Dilution Rate | Sodium (Na+) mmol/L | Potassium (K+) mmol/L | Calcium (Ca+2) mmol/L | Magnesium (Mg+2) mmol/L | Chloride (Cl-) mmol/L | Acetic Acid (Ac-) mmol/L | HCO <sub>3</sub> mmol/L | Glucose (C6H12O6) mmol/L |
|---------------------|---------------|---------------------|-----------------------|-----------------------|-------------------------|-----------------------|--------------------------|-------------------------|--------------------------|
| Insprazol A 1001    | 1+34          | 140                 | 2                     | 1,5                   | 0,5                     | 111                   | 3                        | 32                      | 5,55                     |
| Insprazol A 1002    | 1+34          | 138                 | 2                     | 1                     | 0,5                     | 108                   | 3                        | 32                      | 5,55                     |
| Insprazol A 1003    | 1+34          | 138                 | 1                     | 1,25                  | 0,5                     | 107,5                 | 3                        | 32                      | 5,55                     |
| Insprazol A 1004    | 1+34          | 140                 | 2                     | 1,5                   | 0,5                     | 111                   | 3                        | 32                      | -                        |
| Insprazol A 1005    | 1+34          | 138                 | 2                     | 1,75                  | 0,5                     | 109,5                 | 3                        | 32                      | -                        |
| Insprazol A 1006    | 1+34          | 138                 | 2                     | 1,75                  | 0,5                     | 109,5                 | 3                        | 32                      | 5,55                     |
| Insprazol A 1007    | 1+34          | 138                 | 2                     | 1,25                  | 0,5                     | 108,5                 | 3                        | 32                      | 5,55                     |
| Insprazol A 1008    | 1+34          | 138                 | 2                     | 1,5                   | 0,5                     | 109                   | 3                        | 32                      | 5,55                     |
| Insprazol A 1009    | 1+34          | 138                 | 3                     | 1,5                   | 0,5                     | 110                   | 3                        | 32                      | 5,55                     |
| Insprazol A 1010    | 1+34          | 138                 | 3                     | 1                     | 0,5                     | 109                   | 3                        | 32                      | 11,1                     |
| Insprazol A 1013    | 1/34          | 140                 | 2                     | 1,25                  | 0,5                     | 110,5                 | 3                        | 32                      | 5,55                     |
| Insprazol A 1015    | 1/34          | 140                 | 2                     | 1,25                  | 0,5                     | 110,5                 | 3                        | 32                      | -                        |
| Insprazol A 1016    | 1/34          | 138                 | 2                     | 1                     | 0,5                     | 108                   | 3                        | 32                      | -                        |
| Insprazol A 1020    | 1/34          | 138                 | 0                     | 1,5                   | 0,5                     | 107                   | 3                        | 32                      | 0                        |
| Insprazol A 1021    | 1/34          | 138                 | 0                     | 1,5                   | 0,5                     | 107                   | 3                        | 32                      | 5,55                     |
| Insprazol A 1027    | 1/34          | 138                 | 2                     | 1,25                  | 0,5                     | 108,5                 | 3                        | 32                      | -                        |
| Insprazol A 1034    | 1/34          | 138                 | 1                     | 1,5                   | 0,5                     | 108                   | 3                        | 32                      | 11,1                     |
| Insprazol A 1035    | 1/34          | 138                 | 2                     | 1,5                   | 0,5                     | 109                   | 3                        | 32                      | -                        |
| Insprazol A 1045    | 1/34          | 138                 | 0                     | 1,75                  | 0,5                     | 110,5                 | 3                        | 32                      | 5,55                     |

#### 1+35,83

| Product Name / Code | Dilution Rate | Sodium (Na+) mmol/L | Potassium (K+) mmol/L | Calcium (Ca+2) mmol/L | Magnesium (Mg+2) mmol/L | Chloride (Cl-) mmol/L | Acetic Acid (Ac-) mmol/L | HCO <sub>3</sub> mmol/L | Glucose (C6H12O6) mmol/L |
|---------------------|---------------|---------------------|-----------------------|-----------------------|-------------------------|-----------------------|--------------------------|-------------------------|--------------------------|
| Insprazol A 1150    | 1+35,83       | 140                 | 2                     | 1,75                  | 0,5                     | 107,5                 | 4                        | 35                      | -                        |
| Insprazol A 1151    | 1+35,83       | 140                 | 2                     | 1,75                  | 0,5                     | 107,5                 | 4                        | 35                      | 5,55                     |
| Insprazol A 1152    | 1+35,83       | 140                 | 2                     | 1,5                   | 0,5                     | 107                   | 4                        | 35                      | -                        |
| Insprazol A 1153    | 1+35,83       | 140                 | 2                     | 1,5                   | 0,5                     | 107                   | 4                        | 35                      | 5,55                     |
| Insprazol A 1154    | 1+35,83       | 140                 | 2                     | 1,25                  | 0,5                     | 106,5                 | 4                        | 35                      | 5,55                     |
| Insprazol A 1155    | 1+35,83       | 140                 | 1                     | 1,5                   | 0,5                     | 106                   | 5                        | 34                      | -                        |

#### 1+44

| Product Name / Code | Dilution Rate | Sodium (Na+) mmol/L | Potassium (K+) mmol/L | Calcium (Ca+2) mmol/L | Magnesium (Mg+2) mmol/L | Chloride (Cl-) mmol/L | Acetic Acid (Ac-) mmol/L | HCO <sub>3</sub> mmol/L | Glucose (C6H12O6) mmol/L |
|---------------------|---------------|---------------------|-----------------------|-----------------------|-------------------------|-----------------------|--------------------------|-------------------------|--------------------------|
| Insprazol A 1101    | 1+44          | 138                 | 2                     | 1,25                  | 0,5                     | 108,5                 | 3                        | 32                      | -                        |
| Insprazol A 1102    | 1+44          | 138                 | 2                     | 1,25                  | 0,5                     | 108,5                 | 3                        | 32                      | 5,5                      |
| Insprazol A 1103    | 1+44          | 138                 | 2                     | 1,5                   | 0,5                     | 109                   | 3                        | 32                      | -                        |
| Insprazol A 1104    | 1+44          | 138                 | 2                     | 1,5                   | 0,5                     | 109                   | 3                        | 32                      | 5,5                      |
| Insprazol A 1105    | 1+44          | 138                 | 2                     | 1,75                  | 0,5                     | 109,5                 | 3                        | 32                      | -                        |
| Insprazol A 1106    | 1+44          | 138                 | 2                     | 1,75                  | 0,5                     | 109,5                 | 3                        | 32                      | 5,5                      |
| Insprazol A 1107    | 1+44          | 138                 | 3                     | 1,25                  | 0,5                     | 109,5                 | 3                        | 32                      | 5,55                     |
| Insprazol A 1108    | 1+44          | 138                 | 3                     | 1,5                   | 0,5                     | 110                   | 3                        | 32                      | 5,55                     |
| Insprazol A 1109    | 1+44          | 140                 | 2                     | 1,5                   | 0,5                     | 109                   | 3                        | 34                      | 5,55                     |
| Insprazol A 1110    | 1+44          | 138                 | 3                     | 1,25                  | 0,5                     | 109,5                 | 3                        | 32                      | -                        |

## OUR PRODUCTS | BASIC CONCENTRATES

- Basic haemodialysis concentrate for acute or chronic renal failure patients.
- Used by choosing an appropriate Insprasol Acidic Concentrate and diluting it with purified water.
- Canister material: polyethylene (HDPE).
- Shelf life: 24 months.

## LIQUID BICARBONATE CONCENTRATES

| Product Name / Code | Dilution Rate | NaHCO <sub>3</sub> |      | NaCl   |       | Trading Sale (Liters) |
|---------------------|---------------|--------------------|------|--------|-------|-----------------------|
|                     |               | mmol/L             | gr/L | mmol/L | gr/L  |                       |
| Insprasol B35       | 1+34 or 1+44  | 35                 | 84   | N/A    | N/A   | 5,6,10                |
| Insprasol B39       | 1+35,83       | 39                 | 66   | 26     | 30,58 | 6,10                  |



## DRY BICARBONATE CONCENTRATES

| Product Name / Code                            | NaHCO <sub>3</sub> (kgs) | Concentrate (Liters) |
|--|--------------------------|----------------------|
| Insprabag Haemodialysis Sodium Bicarbonate Bag | 5                        | 59,5                 |
| Insprabag Haemodialysis Sodium Bicarbonate Bag | 8,40                     | 100                  |
| Insprabag Haemodialysis Sodium Bicarbonate Bag | 25                       | 297,6                |





## OUR PRODUCTS | SODIUM BICARBONATE

### INSPRACART

- Contains sodium bicarbonate powder according to the specifications of Ph.Eur and USP.
- Used for obtaining basic bicarbonate haemodialysis concentrate for extra-corporeal bicarbonate haemodialysis.
- Can be used in all dialysis machines (Baxter/Gambro, B.Braun, Nipro, Nikkiso etc.) with appropriate cartridge holders.
- Each 84.0 g of  $\text{NaHCO}_3$  (sodium bicarbonate) from the Inspracart can be used to produce 1 liter of basic concentrate. Depending on the size of the cartridge used, you can produce 6.55 - 11.43L of basic concentrate.

The acidic concentrate, the alkaline concentrate saturated by dissolution and the dialysis water can be used in the following typical mixing ratios: 1 + 1.225 + 32.775 / 1 + 1.775 + 42.225 / 1 + 1.575 + 42.425.

Depending on the mixing ratio, between 25.35L and up to 28.57L ready-to-use dialysis fluid can be made from one liter of basic concentrate for the treatment.

- Cartridge material: polypropylene (PP).
- Shelf life: 24 months.

## OUR PRODUCTS | SODIUM BICARBONATE

**Solution amounts which can be obtained from Inspracart:**

| Product    | NaHCO <sub>3</sub> | Dialysis Solution (Liters) |
|------------|--------------------|----------------------------|
| Inspracart | 550 g              | 160-180                    |
| Inspracart | 650 g              | 190-210                    |
| Inspracart | 720 g              | 210-235                    |
| Inspracart | 750 g              | 220-245                    |
| Inspracart | 760 g              | 225-250                    |
| Inspracart | 850 g              | 252-283                    |
| Inspracart | 920 g              | 270-305                    |
| Inspracart | 960 g              | 285-315                    |



## OUR PRODUCTS | SODIUM BICARBONATE

### INSPRABAG

- Contains sodium bicarbonate powder according to the specifications of Ph.Eur and USP.
- Used for obtaining basic bicarbonate haemodialysis concentrate for extra-corporal bicarbonate haemodialysis.
- Can be used with Fresenius haemodialysis machines.
- Each 84.0 g of  $\text{NaHCO}_3$  (sodium bicarbonate) from the Inspracart can be used to produce 1 liter of basic concentrate. Depending on the size of the bag, you can produce 7.74 - 10.71L of basic concentrate.

The acidic concentrate, the alkaline concentrate saturated by dissolution and the dialysis water can be used in the following typical mixing ratios: 1 + 1.225 + 32.775 / 1 + 1.775 + 42.225 / 1 + 1.575 + 42.425.

Depending on the mixing ratio, between 25.35L and up to 28.57L ready-to-use dialysis fluid can be made from one liter of basic concentrate for the treatment.

- Bag material: polyethylene (LDPE).
- Shelf life: 24 months.

#### Solution amounts which can be obtained from Insprabag:

| Product   | $\text{NaHCO}_3$ | Dialysis Solution (Liters) |
|-----------|------------------|----------------------------|
| Insprabag | 650 g            | 190-210                    |
| Insprabag | 900 g            | 265-300                    |





## OUR PRODUCTS | DIALYSIS MACHINE DISINFECTANTS

- For thermo-chemical disinfection and decalcification of haemodialysis machines with recirculation.
- Excellent disinfection performance in combination with thermal disinfection.
- Colorless and odorless.
- Possible to store long term and easy to control under various conditions due to excellent stability.

### Full effectiveness for:

- Bactericidal (S.aureus, P.aeruginosa, E.hirae) - EN -13727 EN 14561.
- Fungicidal (C.albicans, A.niger) - EN 13624.
- Mycobacterium terrae (ATCC 15755), Mycobacterium avium (ATCC 15769) - TS EN 14348.
- Virucidal (Poliovirus type1-, Adenovirus Type 5- and Murine Norovirus) - TS EN 14476.
- Blood residuals and calcium / magnesium deposits.



| Product Name / Code | Citric Acid % | Malic Acid % | Lactic Acid % | Purified Water (R.O) |
|---------------------|---------------|--------------|---------------|----------------------|
| Inspradez C.M.L 2,5 | 21            | 2,5          | 2,5           | Enough Quantity      |
| Inspradez C50       | 50            | -            | -             | Enough Quantity      |

## PACKAGING

| Insprasol Acid and Basic Concentrates & Inspradez Machine Disinfectants Packaging |      |            |            |              |              |         |
|---|------|------------|------------|--------------|--------------|---------|
| Product   | Size | PCS/Box    | Box/Pallet | Pallet/20'DC | Pallet/40'DC | Truck   |
| Insprasol Haemodialysis Acid Concentrates   | 5 L  | 2/1 or 4/1 | 150/1      | 10/1         | 21/1         | 24 tons |
|   | 8 L  | 2/1        | 100/1      |              |              |         |
|   | 10 L | 2/1        | 100/1      |              |              |         |
| Insprasol Haemodialysis Basic Concentrates  | 5 L  | 2/1 or 4/1 | 150/1      |              |              |         |
|   | 6 L  | 4/1        | 144/1      |              |              |         |
|   | 10 L | 2/1        | 100/1      |              |              |         |
| Inspradez Haemodialysis Machine Disinfectants C.M.L 2,5 / C50                     | 5 L  | 2/1        | 160/1      |              |              |         |
|   | 10 L | 2/1        | 100/1      |              |              |         |

| Insprasol Acid Concentrates Packaging without Boxes |        |            |              |              |         |
|---|--------|------------|--------------|--------------|---------|
| Product   | Size   | PCS/Pallet | Pallet/20'DC | Pallet/40'DC | Truck   |
| Insprasol Haemodialysis Acid Concentrates           | 5 L    | 150/1      | 10/1         | 21/1         | 24 tons |
|   | 8 L    | 120/1      |              |              |         |
|   | 10 L   | 100/1      |              |              |         |
|   | 1000 L | 1/1        |              |              |         |

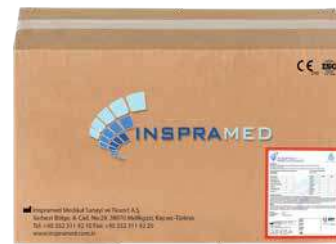
| Insprasol Basic Concentrates Packaging without Boxes |      |            |              |              |         |
|--|------|------------|--------------|--------------|---------|
| Product  | Size | PCS/Pallet | Pallet/20'DC | Pallet/40'DC | Truck   |
| Insprasol Haemodialysis Basic Concentrates           | 5 L  | 150/1      | 10/1         | 21/1         | 24 tons |
|  | 6 L  | 150/1      |              |              |         |
|  | 10 L | 100/1      |              |              |         |



## PACKAGING

### Insprasol Haemodialysis Powder Acid Concentrate Packaging

| Product  | Size | PCS/Pallet | Pallet/20'DC | Pallet/40'DC | Truck   |
|--|------|------------|--------------|--------------|---------|
| Insprasol Haemodialysis Powder Acid Concentrates | 1/1  | 40/1       | 10/1         | 21/1         | 24 tons |



### Insprasol Powder Basic Concentrate Packaging

| Product                             | Size     | PCS/Box | Case/Pallet | Pallet/20'DC | Pallet/40'DC | Truck   |
|-------------------------------------|----------|---------|-------------|--------------|--------------|---------|
| Insprasol Powder Basic Concentrates | 5 kgs    | 5/1     | 32/1        | 10/1         | 21/1         | 24 tons |
|                                     | 8,40 kgs | 4/1     | 32/1        | 10/1         | 21/1         |         |
|                                     | 25 kgs   | -       | 49/1        | 10/1         | 21/1         |         |



## PACKAGING

| Insprazol Haemodialysis Sodium Bicarbonate Cartridge Packaging |       |         |                     |              |              |         |
|--|-------|---------|---------------------|--------------|--------------|---------|
| Product  | Size  | PCS/Box | Box/ Pallet         | Pallet/20'DC | Pallet/40'HC | Truck   |
| Inspracart Haemodialysis Sodium Bicarbonate Cartridges         | 550 g | 10/1    | 100/1<br>or<br>96/1 | 10/1         | 21/1         | 24 tons |
|  | 650 g |         |                     |              |              |         |
|  | 720 g |         |                     |              |              |         |
|  | 750 g |         |                     |              |              |         |
|  | 760 g |         |                     |              |              |         |
|  | 850 g |         |                     |              |              |         |
|  | 900 g |         |                     |              |              |         |
|  | 920 g |         |                     |              |              |         |
|  | 960 g |         |                     |              |              |         |



| Insprazol Haemodialysis Sodium Bicarbonate Bag Packaging |       |         |             |              |              |         |
|--|-------|---------|-------------|--------------|--------------|---------|
| Product  | Size  | PCS/Box | Box/ Pallet | Pallet/20'DC | Pallet/40'HC | Truck   |
| Insprazol Haemodialysis Sodium Bicarbonate Bags          | 650 g | 16/1    | 64/1        | 11/1         | 24/1         | 24 tons |
|  | 900 g | 12/1    | 64/1        |              |              |         |





# DIALYSIS SOLUTIONS

FORMULATED AND MANUFACTURED FOR THE  
HIGHEST LEVEL OF PATIENT CARE.



**PROVEN COMPETENCE**  
IN MORE THAN  
**30 INTERNATIONAL MARKETS**



[www.inspramed.com.tr](http://www.inspramed.com.tr)