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	**:Insprasol 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	**:Insprasol 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**

PRODUCT NAME	SODIUM BICARBONATE (Grams)
INSPRACART	550
INSPRACART	650
INSPRACART	720
INSPRACART	750
INSPRACART	760
INSPRACART	850
INSPRACART	920
INSPRACART	960

- **INSPRABAG**

PRODUCT NAME	SODIUM BICARBONATE (Grams)
INSPRABAG	650
INSPRABAG	840
INSPRABAG	900
INSPRABAG	5000 (5 kgs)
INSPRABAG	8400 (8,40 kgs)
INSPRABAG	25000 (25 kgs)

- **INSPRADEZ**

PRODUCT CODE	FORMULATION	PACKAGING AMOUNTS
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 1041: 2008 + A1: 2013 Information supplied by the manufacturer of medical devices
- EN 10993-1:2018 Biological evaluation of medical devices.
- MDCG Guidance
- EN 15223: 2016 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 13624:2014 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)
- 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 12353:2013 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