

EC COMPLIANCE DECLARATION

no. MDT/8

As per Act no. 22/1997 Sb. on technical requirements for products as amended and as per Government Decree no. 54/2015 Sb. which governs technical requirements for medical devices as amended and in harmony with the requirements of the Council Directive 93/42/EEC for medical devices

Manufacturer: **MEDITES PHARMA, spol. s r. o.**
 Registered office: **Rožnov pod Radhoštěm, 1. máje 2625, Czech Republic**
CZ - 756 61
 Company registration number: **45194815**

hereby declares that the medical device

Haemodialysis Concentrate for Bicarbonate Dialysis - acid BIC AF,

which types are listed in the appendix "A", which is an inseparable part of this declaration,

meets essential requirements defined in attachment 1 to the Government Decree number 54/2015 Sb. and the Council Directive 93/42/EEC which requirements apply to it with regard to the intended use.

Description of the medical device: Haemodialysis Concentrate for Bicarbonate Dialysis – acid BIC AF are supplied in 5 or 10 litre polyethylene canisters, closed by a threaded cap with a one-time safety lock.

Intended use: hemodialysis concentrates serves for preparation of dialytic solution in a dialyzer.

Grade as per the attachment no. 9 of the Government Decree 54/2015 Sb.:
classification rule no. 3: IIb

Non-invasive medical device intended for adjusting biological or chemical composition of blood, other bodily fluids, or other fluids intended for intravenous drip.

Following requirements are met during production and distribution:

ČSN EN ISO 13 485 ed. 2: 2016, ČSN EN ISO 14 971:2012, ČSN EN ISO 15223-1:2017, Czech pharmacopoeia and internal regulations of MEDITES PHARMA spol. s r.o.

The below mentioned notified body participated in assessment of the compliance:

Name: **INSTITUT PRO TESTOVÁNÍ A CERTIFIKACI**
 Registered office: **Třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic**
 Number of notified body: **1023**
 Company registration number: **47910381**

which issued ES Certificate no. 20 0139 QS/NB rev. - (valid from 2020-03-31 to 2024-05-27) as per addendum II 2 of the Council Directive 93/42/EEC.

ES certificate issued for Haemodialysis Concentrates for Bicarbonate Dialysis - acid BIC AF, which are listed in the appendix "A" of this declaration.

In Rožnov pod Radhoštěm, dated 31st March 2020

MEDITES PHARMA
 spol. s r.o.
 756 61 Rožnov pod Radhoštěm



Libuše Franová, executive

Name, title and signature of the manufacturer's responsible person

Supersedes ES compliance declaration no. MDT /8 dated: 10.12.2019

Appendix "A" to ES compliance declaration, which was issued on 31th March 2020:

Haemodialysis Concentrate for Bicarbonate Dialysis - Acidic – BIC AF 306
Haemodialysis Concentrate for Bicarbonate Dialysis - Acidic – NIPROSOL-A BIC AF 306

Haemodialysis Concentrate for Bicarbonate Dialysis - Acidic – BIC AF 311
Haemodialysis Concentrate for Bicarbonate Dialysis - Acidic – NIPROSOL-A BIC AF 311

Haemodialysis Concentrate for Bicarbonate Dialysis - Acidic – BIC AF 313
Haemodialysis Concentrate for Bicarbonate Dialysis - Acidic – NIPROSOL-A BIC AF 313

Haemodialysis Concentrate for Bicarbonate Dialysis - Acidic – BIC AF 315
Haemodialysis Concentrate for Bicarbonate Dialysis - Acidic – NIPROSOL-A BIC AF 315

Haemodialysis Concentrate for Bicarbonate Dialysis - Acidic – BIC AF 318
Haemodialysis Concentrate for Bicarbonate Dialysis - Acidic – NIPROSOL-A BIC AF 318

Haemodialysis Concentrate for Bicarbonate Dialysis - Acidic – BIC AF 320
Haemodialysis Concentrate for Bicarbonate Dialysis - Acidic – NIPROSOL-A BIC AF 320

Haemodialysis Concentrate for Bicarbonate Dialysis - Acidic – BIC AF 322
Haemodialysis Concentrate for Bicarbonate Dialysis - Acidic – NIPROSOL-A BIC AF 322

Haemodialysis Concentrate for Bicarbonate Dialysis - Acidic – BIC AF 325
Haemodialysis Concentrate for Bicarbonate Dialysis - Acidic – NIPROSOL-A BIC AF 325

Haemodialysis Concentrate for Bicarbonate Dialysis - Acidic – BIC AF 327
Haemodialysis Concentrate for Bicarbonate Dialysis - Acidic – NIPROSOL-A BIC AF 327

Haemodialysis Concentrate for Bicarbonate Dialysis - Acidic – BIC AF 329
Haemodialysis Concentrate for Bicarbonate Dialysis - Acidic – NIPROSOL-A BIC AF 329

Haemodialysis Concentrate for Bicarbonate Dialysis - Acidic – BIC AF 330
Haemodialysis Concentrate for Bicarbonate Dialysis - Acidic – NIPROSOL-A BIC AF 330

Haemodialysis Concentrate for Bicarbonate Dialysis - Acidic – BIC AF 506
Haemodialysis Concentrate for Bicarbonate Dialysis - Acidic – NIPROSOL-A BIC AF 506

Haemodialysis Concentrate for Bicarbonate Dialysis - Acidic – BIC AF 511
Haemodialysis Concentrate for Bicarbonate Dialysis - Acidic – NIPROSOL-A BIC AF 511

Haemodialysis Concentrate for Bicarbonate Dialysis - Acidic – BIC AF 513
Haemodialysis Concentrate for Bicarbonate Dialysis - Acidic – NIPROSOL-A BIC AF 513

Haemodialysis Concentrate for Bicarbonate Dialysis - Acidic – BIC AF 513
Haemodialysis Concentrate for Bicarbonate Dialysis - Acidic – NIPROSOL-A BIC AF 513

Haemodialysis Concentrate for Bicarbonate Dialysis - Acidic – BIC AF 515
Haemodialysis Concentrate for Bicarbonate Dialysis - Acidic – NIPROSOL-A BIC AF 515

Haemodialysis Concentrate for Bicarbonate Dialysis - Acidic – BIC AF 518
Haemodialysis Concentrate for Bicarbonate Dialysis - Acidic – NIPROSOL-A BIC AF 518

Haemodialysis Concentrate for Bicarbonate Dialysis - Acidic – BIC AF 432
Haemodialysis Concentrate for Bicarbonate Dialysis - Acidic – NIPROSOL-A BIC AF 432

Haemodialysis Concentrate for Bicarbonate Dialysis - Acidic – BIC AF 606
Haemodialysis Concentrate for Bicarbonate Dialysis - Acidic – NIPROSOL-A BIC AF 606

Haemodialysis Concentrate for Bicarbonate Dialysis - Acidic – BIC AF 611
Haemodialysis Concentrate for Bicarbonate Dialysis - Acidic – NIPROSOL-A BIC AF 611

Haemodialysis Concentrate for Bicarbonate Dialysis - Acidic – BIC AF 613
Haemodialysis Concentrate for Bicarbonate Dialysis - Acidic – NIPROSOL-A BIC AF 613

Haemodialysis Concentrate for Bicarbonate Dialysis - Acidic – BIC AF 615
Haemodialysis Concentrate for Bicarbonate Dialysis - Acidic – NIPROSOL-A BIC AF 615

Haemodialysis Concentrate for Bicarbonate Dialysis - Acidic – BIC AF 618
Haemodialysis Concentrate for Bicarbonate Dialysis - Acidic – NIPROSOL-A BIC AF 618

Haemodialysis Concentrate for Bicarbonate Dialysis - Acidic – BIC AF 620
Haemodialysis Concentrate for Bicarbonate Dialysis - Acidic – NIPROSOL-A BIC AF 620

Haemodialysis Concentrate for Bicarbonate Dialysis - Acidic – BIC AF 622
Haemodialysis Concentrate for Bicarbonate Dialysis - Acidic – NIPROSOL-A BIC AF 622

Haemodialysis Concentrate for Bicarbonate Dialysis - Acidic – BIC AF 625
Haemodialysis Concentrate for Bicarbonate Dialysis - Acidic – NIPROSOL-A BIC AF 625

Haemodialysis Concentrate for Bicarbonate Dialysis - Acidic – BIC AF 627
Haemodialysis Concentrate for Bicarbonate Dialysis - Acidic – NIPROSOL-A BIC AF 627

Haemodialysis Concentrate for Bicarbonate Dialysis - Acidic – BIC AF 629
Haemodialysis Concentrate for Bicarbonate Dialysis - Acidic – NIPROSOL-A BIC AF 629

Haemodialysis Concentrate for Bicarbonate Dialysis - Acidic – BIC AF 630
Haemodialysis Concentrate for Bicarbonate Dialysis - Acidic – NIPROSOL-A BIC AF 630