EC COMPLIANCE DECLARATION
no. MDT/2

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 CITRASATE® BIC,

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 Concentrates for Bicarbonate Dialysis - acid CITRASATE® BIC are supplied in 5 or 10 litre polyethylene canisters, closed by a threaded cap with a one-time safety lock.

Intended use: Haemodialysis 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 CITRASATE® BIC, which are listed in the appendix "A" of this declaration.

In Rožnov pod Radhoštěm, dated 31th 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 /2 dated 10.12.2019

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

Haemodialysis Concentrate for Bicarbonate Dialysis - acid CITRASATE® BIC 301
Haemodialysis Concentrate for Bicarbonate Dialysis - acid CITRASATE® BIC 302
Haemodialysis Concentrate for Bicarbonate Dialysis - acid CITRASATE® BIC 303
Haemodialysis Concentrate for Bicarbonate Dialysis - acid CITRASATE® BIC 304
Haemodialysis Concentrate for Bicarbonate Dialysis - acid CITRASATE® BIC 305
Haemodialysis Concentrate for Bicarbonate Dialysis - acid CITRASATE® BIC 306
Haemodialysis Concentrate for Bicarbonate Dialysis - acid CITRASATE® BIC 307
Haemodialysis Concentrate for Bicarbonate Dialysis - acid CITRASATE® BIC 308
Haemodialysis Concentrate for Bicarbonate Dialysis - acid CITRASATE® BIC 309
Haemodialysis Concentrate for Bicarbonate Dialysis - acid CITRASATE® BIC 310
Haemodialysis Concentrate for Bicarbonate Dialysis - acid CITRASATE® BIC 311
Haemodialysis Concentrate for Bicarbonate Dialysis - acid CITRASATE® BIC 312
Haemodialysis Concentrate for Bicarbonate Dialysis - acid CITRASATE® BIC 313
Haemodialysis Concentrate for Bicarbonate Dialysis - acid CITRASATE® BIC 314
Haemodialysis Concentrate for Bicarbonate Dialysis - acid CITRASATE® BIC 315
Haemodialysis Concentrate for Bicarbonate Dialysis - acid CITRASATE® BIC 316
Haemodialysis Concentrate for Bicarbonate Dialysis - acid CITRASATE® BIC 317
Haemodialysis Concentrate for Bicarbonate Dialysis - acid CITRASATE® BIC 318
Haemodialysis Concentrate for Bicarbonate Dialysis - acid CITRASATE® BIC 319
Haemodialysis Concentrate for Bicarbonate Dialysis - acid CITRASATE® BIC 320
Haemodialysis Concentrate for Bicarbonate Dialysis - acid CITRASATE® BIC 321
Haemodialysis Concentrate for Bicarbonate Dialysis - acid CITRASATE® BIC 322
Haemodialysis Concentrate for Bicarbonate Dialysis - acid CITRASATE® BIC 323
Haemodialysis Concentrate for Bicarbonate Dialysis - acid CITRASATE® BIC 324
Haemodialysis Concentrate for Bicarbonate Dialysis - acid CITRASATE® BIC 325
Haemodialysis Concentrate for Bicarbonate Dialysis - acid CITRASATE® BIC 326
Haemodialysis Concentrate for Bicarbonate Dialysis - acid CITRASATE® BIC 327
Haemodialysis Concentrate for Bicarbonate Dialysis - acid CITRASATE® BIC 328
Haemodialysis Concentrate for Bicarbonate Dialysis - acid CITRASATE® BIC 329

Haemodialysis Concentrate for Bicarbonate Dialysis – acid CITRASATE® BIC 413
Haemodialysis Concentrate for Bicarbonate Dialysis – acid CITRASATE® BIC 420

Haemodialysis Concentrate for Bicarbonate Dialysis – acid NIPROSOL-A CITRASATE® 301
Haemodialysis Concentrate for Bicarbonate Dialysis – acid NIPROSOL-A CITRASATE® 302
Haemodialysis Concentrate for Bicarbonate Dialysis – acid NIPROSOL-A CITRASATE® 303
Haemodialysis Concentrate for Bicarbonate Dialysis – acid NIPROSOL-A CITRASATE® 304
Haemodialysis Concentrate for Bicarbonate Dialysis – acid NIPROSOL-A CITRASATE® 305
Haemodialysis Concentrate for Bicarbonate Dialysis – acid NIPROSOL-A CITRASATE® 306
Haemodialysis Concentrate for Bicarbonate Dialysis – acid NIPROSOL-A CITRASATE® 307
Haemodialysis Concentrate for Bicarbonate Dialysis – acid NIPROSOL-A CITRASATE® 308
Haemodialysis Concentrate for Bicarbonate Dialysis – acid NIPROSOL-A CITRASATE® 309
Haemodialysis Concentrate for Bicarbonate Dialysis – acid NIPROSOL-A CITRASATE® 310
Haemodialysis Concentrate for Bicarbonate Dialysis – acid NIPROSOL-A CITRASATE® 311
Haemodialysis Concentrate for Bicarbonate Dialysis – acid NIPROSOL-A CITRASATE® 312
Haemodialysis Concentrate for Bicarbonate Dialysis – acid NIPROSOL-A CITRASATE® 313
Haemodialysis Concentrate for Bicarbonate Dialysis – acid NIPROSOL-A CITRASATE® 314
Haemodialysis Concentrate for Bicarbonate Dialysis – acid NIPROSOL-A CITRASATE® 315
Haemodialysis Concentrate for Bicarbonate Dialysis – acid NIPROSOL-A CITRASATE® 316
Haemodialysis Concentrate for Bicarbonate Dialysis – acid NIPROSOL-A CITRASATE® 317
Haemodialysis Concentrate for Bicarbonate Dialysis – acid NIPROSOL-A CITRASATE® 318
Haemodialysis Concentrate for Bicarbonate Dialysis – acid NIPROSOL-A CITRASATE® 319
Haemodialysis Concentrate for Bicarbonate Dialysis – acid NIPROSOL-A CITRASATE® 320
Haemodialysis Concentrate for Bicarbonate Dialysis – acid NIPROSOL-A CITRASATE® 321
Haemodialysis Concentrate for Bicarbonate Dialysis – acid NIPROSOL-A CITRASATE® 322
Haemodialysis Concentrate for Bicarbonate Dialysis – acid NIPROSOL-A CITRASATE® 323
Haemodialysis Concentrate for Bicarbonate Dialysis – acid NIPROSOL-A CITRASATE® 324
Haemodialysis Concentrate for Bicarbonate Dialysis – acid NIPROSOL-A CITRASATE® 325
Haemodialysis Concentrate for Bicarbonate Dialysis – acid NIPROSOL-A CITRASATE® 326
Haemodialysis Concentrate for Bicarbonate Dialysis – acid NIPROSOL-A CITRASATE® 327
Haemodialysis Concentrate for Bicarbonate Dialysis – acid NIPROSOL-A CITRASATE® 328
Haemodialysis Concentrate for Bicarbonate Dialysis – acid NIPROSOL-A CITRASATE® 329

Haemodialysis Concentrate for Bicarbonate Dialysis – acid NIPROSOL-A CITRASATE® 413
Haemodialysis Concentrate for Bicarbonate Dialysis – acid NIPROSOL-A CITRASATE® 420