

## EC COMPLIANCE DECLARATION

### no. MDT/4

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 Concentrates,

**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 are supplied in 5 or 10 litre polyethylene canisters, closed by a threaded cap with a one-time safety lock. Or in PE containers closed by screw cap and outflow valve.

**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, which are listed in the appendix "A" of this declaration.

In Rožnov pod Radhoštěm, dated 31<sup>th</sup> 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 /4 dated: 10.12.2019

**Appendix "A" to ES compliance declaration, which was issued on 31<sup>st</sup> March 2020:**

**Haemodialysis Concentrates for Bicarbonate Dialysis**

Haemodialysis Concentrates for Bicarbonate Dialysis – alkalic BIA-F 8,4% sol.

Haemodialysis Concentrates for Bicarbonate Dialysis - acid BIK-F 01 sol.  
Haemodialysis Concentrates for Bicarbonate Dialysis - acid BIK-F 02 sol.  
Haemodialysis Concentrates for Bicarbonate Dialysis - acid BIK-F 04 sol.  
Haemodialysis Concentrates for Bicarbonate Dialysis - acid BIK-F 05 sol.  
Haemodialysis Concentrates for Bicarbonate Dialysis - acid BIK-F 06 sol.  
Haemodialysis Concentrates for Bicarbonate Dialysis - acid BIK-F 08 sol.  
Haemodialysis Concentrates for Bicarbonate Dialysis - acid BIK-F 09 sol.  
Haemodialysis Concentrates for Bicarbonate Dialysis - acid BIK-F 10 sol.  
Haemodialysis Concentrates for Bicarbonate Dialysis - acid BIK-F 11 sol.  
Haemodialysis Concentrates for Bicarbonate Dialysis - acid BIK-F 17 sol.  
Haemodialysis Concentrates for Bicarbonate Dialysis - acid BIK-F 18 sol.  
Haemodialysis Concentrates for Bicarbonate Dialysis - acid BIK-F 19 sol.  
Haemodialysis Concentrates for Bicarbonate Dialysis - acid BIK-F 20 sol.  
Haemodialysis Concentrates for Bicarbonate Dialysis - acid BIK-F 30 sol.  
Haemodialysis Concentrates for Bicarbonate Dialysis - acid BIK-F 31 sol.  
Haemodialysis Concentrates for Bicarbonate Dialysis - acid BIK-F 32 sol.  
Haemodialysis Concentrates for Bicarbonate Dialysis - acid BIK-F 33 sol.  
Haemodialysis Concentrates for Bicarbonate Dialysis - acid BIK-F 39 sol.  
Haemodialysis Concentrates for Bicarbonate Dialysis - acid BIK-F 40 sol.  
Haemodialysis Concentrates for Bicarbonate Dialysis - acid BIK-F 51 sol.  
Haemodialysis Concentrates for Bicarbonate Dialysis - acid BIK-F 52 sol.  
Haemodialysis Concentrates for Bicarbonate Dialysis - acid BIK-F 54 sol.  
Haemodialysis Concentrates for Bicarbonate Dialysis - acid BIK-F 58 sol.  
Haemodialysis Concentrates for Bicarbonate Dialysis - acid BIK-F 59 sol.  
Haemodialysis Concentrates for Bicarbonate Dialysis - acid BIK-F 60 sol.  
Haemodialysis Concentrates for Bicarbonate Dialysis - acid BIK-F 61 sol.  
Haemodialysis Concentrates for Bicarbonate Dialysis - acid BIK-F 62 sol.  
Haemodialysis Concentrates for Bicarbonate Dialysis - acid BIK-F 63 sol.  
Haemodialysis Concentrates for Bicarbonate Dialysis - acid BIK-F 64 sol.  
Haemodialysis Concentrates for Bicarbonate Dialysis - acid BIK-F 65 sol.  
Haemodialysis Concentrates for Bicarbonate Dialysis - acid BIK-F 66 sol.

Haemodialysis Concentrates for Bicarbonate Dialysis - acid BIK 112 sol.  
Haemodialysis Concentrates for Bicarbonate Dialysis - acid BIK 114 sol.  
Haemodialysis Concentrates for Bicarbonate Dialysis - acid BIK 120 sol.  
Haemodialysis Concentrates for Bicarbonate Dialysis - acid BIK 121 sol.  
Haemodialysis Concentrates for Bicarbonate Dialysis - acid BIK 122 sol.  
Haemodialysis Concentrates for Bicarbonate Dialysis - acid BIK 123 sol.  
Haemodialysis Concentrates for Bicarbonate Dialysis - acid BIK 124 sol.  
Haemodialysis Concentrates for Bicarbonate Dialysis - acid BIK 125 sol.  
Haemodialysis Concentrates for Bicarbonate Dialysis - acid BIK 131 sol.  
Haemodialysis Concentrates for Bicarbonate Dialysis - acid BIK 132 sol.  
Haemodialysis Concentrates for Bicarbonate Dialysis - acid BIK 133 sol.  
Haemodialysis Concentrates for Bicarbonate Dialysis - acid BIK 134 sol.  
Haemodialysis Concentrates for Bicarbonate Dialysis - acid BIK 142 sol.  
Haemodialysis Concentrates for Bicarbonate Dialysis - acid BIK 143 sol.  
Haemodialysis Concentrates for Bicarbonate Dialysis - acid BIK 144 sol.

Haemodialysis Concentrates for Bicarbonate Dialysis - acid BIK 221 sol.

Haemodialysis Concentrates for Bicarbonate Dialysis - acid BIK 222 sol.  
Haemodialysis Concentrates for Bicarbonate Dialysis - acid BIK 223 sol.

Haemodialysis Concentrates for Bicarbonate Dialysis – alkalic NIPROSOL-B 8,4%  
Haemodialysis Concentrates for Bicarbonate Dialysis - acid NIPROSOL-A F 01  
Haemodialysis Concentrates for Bicarbonate Dialysis - acid NIPROSOL-A F 02  
Haemodialysis Concentrates for Bicarbonate Dialysis - acid NIPROSOL-A F 04  
Haemodialysis Concentrates for Bicarbonate Dialysis - acid NIPROSOL-A F 05  
Haemodialysis Concentrates for Bicarbonate Dialysis - acid NIPROSOL-A F 06  
Haemodialysis Concentrates for Bicarbonate Dialysis - acid NIPROSOL-A F 08  
Haemodialysis Concentrates for Bicarbonate Dialysis - acid NIPROSOL-A F 09  
Haemodialysis Concentrates for Bicarbonate Dialysis - acid NIPROSOL-A F 10  
Haemodialysis Concentrates for Bicarbonate Dialysis - acid NIPROSOL-A F 11  
Haemodialysis Concentrates for Bicarbonate Dialysis - acid NIPROSOL-A F 17  
Haemodialysis Concentrates for Bicarbonate Dialysis - acid NIPROSOL-A F 18  
Haemodialysis Concentrates for Bicarbonate Dialysis - acid NIPROSOL-A F 19  
Haemodialysis Concentrates for Bicarbonate Dialysis - acid NIPROSOL-A F 20  
Haemodialysis Concentrates for Bicarbonate Dialysis - acid NIPROSOL-A F 30  
Haemodialysis Concentrates for Bicarbonate Dialysis - acid NIPROSOL-A F 31  
Haemodialysis Concentrates for Bicarbonate Dialysis - acid NIPROSOL-A F 32  
Haemodialysis Concentrates for Bicarbonate Dialysis - acid NIPROSOL-A F 33  
Haemodialysis Concentrates for Bicarbonate Dialysis - acid NIPROSOL-A F 39  
Haemodialysis Concentrates for Bicarbonate Dialysis - acid NIPROSOL-A F 40  
Haemodialysis Concentrates for Bicarbonate Dialysis - acid NIPROSOL-A F 51  
Haemodialysis Concentrates for Bicarbonate Dialysis - acid NIPROSOL-A F 52  
Haemodialysis Concentrates for Bicarbonate Dialysis - acid NIPROSOL-A F 54  
Haemodialysis Concentrates for Bicarbonate Dialysis - acid NIPROSOL-A F 58  
Haemodialysis Concentrates for Bicarbonate Dialysis - acid NIPROSOL-A F 59  
Haemodialysis Concentrates for Bicarbonate Dialysis - acid NIPROSOL-A F 60  
Haemodialysis Concentrates for Bicarbonate Dialysis - acid NIPROSOL-A F 61  
Haemodialysis Concentrates for Bicarbonate Dialysis - acid NIPROSOL-A F 62  
Haemodialysis Concentrates for Bicarbonate Dialysis - acid NIPROSOL-A F 63  
Haemodialysis Concentrates for Bicarbonate Dialysis - acid NIPROSOL-A F 64  
Haemodialysis Concentrates for Bicarbonate Dialysis - acid NIPROSOL-A F 65  
Haemodialysis Concentrates for Bicarbonate Dialysis - acid NIPROSOL-A F 66