EC Declaration of Conformity
No. MDT/1

As per Act no. 22/1997 Sb. on technical requirements for products as amended and in accordance with the requirements of Council Directive 93/42/EEC on medical devices (hereinafter referred to as "Directive 93/42/EEC")

Manufacturer: **MEDITES PHARMA, spol. s r. o.**
Registered office: **Rožnov pod Radhoštěm, 1. máje 2635, Czech Republic**
CZ - 756 61
Company registration number: **45194815**

hereby declares that the sterile medical devices

CITRASOL
the variants and commercial names of which are listed in the appendix "A", which is an inseparable part of this declaration,

meets essential requirements defined in attachment I to the Council Directive 93/42/EEC which requirements apply to it with regard to the intended use.

Description of the medical device:

The medical device CITRASOL 4% (Natrii citras 4%) is supplied in PP bags of 250 ml in volume (filled volume 250 ml), 1 000 ml (filled volume 1 000 ml) and 2 000 ml (filled volume 1 500 ml and 2 000 ml). The bags are closed with 2 connectors and packed individually in a wrapping bag.

The medical device CITRASOL 0.5% (Natrii citras 0.5 %) is supplied in PP bags of 5000 ml in volume (filled volume 5 000 ml). The bags are closed with 2 connectors and packed individually in a wrapping bag.

The medical device CITRASOL ACD-A is supplied in PP bags of 250 ml in volume (filled volume 250 ml), 500 ml (filled volume 500 ml) and 1 000 ml (filled volume 750 ml). The bags are closed with 2 connectors and packed into a wrapping bag.

The medical device CITRASOL CPD50 is supplied in PP bags of 250 ml in volume (filled volume 150 ml and 250 ml). The bags are closed with 2 connectors and packed into a wrapping bag.

The medical device is sterile, clear, and free of bacterial endotoxines.

Intended use:
The medical devices CITRASOL 4% and CITRASOL 0.5% are used anticoagulation of whole blood during continuous elimination methods which replace renal functions (Continuous Renal Replacement Therapy-CRRT).
The medical device CITRASOL 4% is also intended for aphaeresis procedures and sorptive methods.

The medical devices CITRASOL ACD-A and CITRASOL CPD50 are solutions intended for anticoagulation of whole blood during automated apheresis.

The risk class as per the attachment no. IX to the Council Directive 93/42/EEC: 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 14 971:2020, ČSN EN ISO 15223-1:2022, Czech pharmacopoeia and internal regulations of MEDITES PHARMA spol. s r.o.

Following notified body has participated in evaluation of the compliance:

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

which issued: EC Certificate No.: 19 0664 QS/NB rev. d (valid from 04/05/2021 to 31/12/2028) according to Annex II of the Council Directive 93/42/EEC.

Appendix "A" to EC compliance declaration:

Variants of medical devices CITRASOL:

	REF
CITRASOL 4% 250 ml	601030
CITRASOL 4% 250 ml	601031
CITRASOL 4% 1 000 ml	601010
CITRASOL 4% 1 000 ml	601011
CITRASOL 4% 1 500 ml	601510
CITRASOL 4% 2 000 ml	601023
CITRASOL 4% 2 000 ml	601021
CITRASOL 0,5% 5 000 ml	603050
CITRASOL ACD- A 250 ml	604030
CITRASOL ACD- A 250 ml	604031
CITRASOL ACD- A 500 ml	604050
CITRASOL ACD- A 500 ml	604051
CITRASOL ACD- A 750 ml	604080
CITRASOL ACD- A 750 ml	604081
CITRASOL CPD50 150 ml	605020
CITRASOL CPD50 150 ml	605021
CITRASOL CPD50 250 ml	605030
CITRASOL CPD50 250 ml	605031

In Rožnov pod Radhoštěm, dated 27th May 2024

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

Libuše Franová, Director
name, title and description of the manufacturer's responsible person

Supersedes EC compliance declaration no. MDT/1 dated: 1.4.2023