MEDITES PHARMA spol. s r.o.
1. máje 2625, CZ-756 61 Rožnov pod Radhoštěm

EC Declaration of Conformity

No. MDT/9

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 2625, Czech Republic**
CZ - 756 61
Company registration number: **45194815**

hereby declares that the sterile medical devices

LACSOL, BICSOL

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 device LACSOL is supplied in 5 000 ml multilayer bag, closed by 2 connectors. The bags are vacuum packed into a wrapping bag.
The device BICSOL is supplied in double chamber PP bags, volume 5 000 ml, closed with 3 connectors. The bags are vacuum packed into a wrapping bag.
The medical devices are sterile, clear and free from bacterial endotoxins, phthalate and latex.

Intended use: The dialysate solutions indicated for renal replacement treatments (RRT).

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 27/05/2024) according to Annex II of the Council Directive 93/42/EEC.

Tel.: +420-571 115 914
Fax: +420-571 602 111
e-mail: medites@meditespharma.cz
http://www.meditespharma.cz
Bank: Komercni banka, a.s., RpR
Account no.: 115-4318200297/0100
IBAN: CZ9601000001154318200297
SWIFT: KOMBCZPPXXX (KOMBCZPP)
Register Court: Regional Court at Ostrava, Section C, File 3235
VAT reg.no. CZ45194815

MEDITES PHARMA
spol. s r.o.

1. máje 2625, CZ-756 61 Rožnov pod Radhoštěm

Appendix "A" to EC compliance declaration:

Variants and trade names

	REF
BICSOL 35 - 110	**723550**
BICSOL 35 - 108 K0	**703550**
BICSOL 35 - 112 K4	**743550**
LACSOL 40 - 107	**541131**
LACSOL 45 - 100	**541133**
LACSOL 45 - 101	**541134**

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

In Rožnov pod Radhoštěm, dated 1st April 2023

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

Supersedes EC compliance declaration no. MDT/9 dated: 4.5.2021

Tel.: +420-571 115 914
Fax: +420-571 602 111
e-mail: medites@meditespharma.cz
http://www.meditespharma.cz
Bank: Komercni banka, a.s., RpR
Account no.: 115-4318200297/0100
IBAN: CZ9601000001154318200297
SWIFT: KOMBCZPPXXX (KOMBCZPP)
Register Court: Regional Court at Ostrava, Section C, File 3235
VAT reg.no. CZ45194815