

## 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 2635, 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.

**Global Medical Device Nomenclature (GMDN):** 35849

#### 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

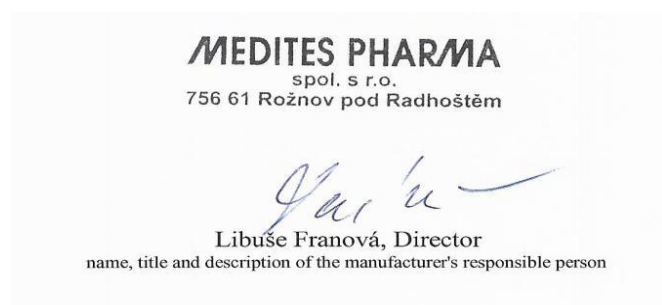
which issued: EC Certificate No.: 19 0664 QS/NB rev. d (valid from 04/05/2021 to 31/12/2028) according to Annex II of the Council Directive 93/42/EEC.

## Appendix "A" to EC compliance declaration:

### Variants 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

In Rožnov pod Radhoštěm, dated 27<sup>th</sup> May 2024



Supersedes EC compliance declaration no. MDT/9 dated: 1.4.2023