

EC Declaration of Conformity

No. MDT/3

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

MEXSOL

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 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 device is sterile, clear and free from bacterial endotoxins.

Intended use:

Sterile calcium-free medical devices in variants and with trade names:

MEXSOL K0 Bi15, MEXSOL K0 Bi20, MEXSOL K2 Bi15, MEXSOL K2 Bi20, MEXSOL K4 Bi15, MEXSOL K4 Bi20, MEXSOL K2 Bi20 P0, MEXSOL K4 Bi20 P0, MEXSOL K2 Bi20 P+, MEXSOL K4 Bi20 P+ are used as dialysis solutions for continuous venous to venous haemodialysis (CVVHD) with citrate anticoagulation using 4% sodium citrate solution and simultaneous administration of calcium.

Sterile calcium-free medical devices in variants and with trade names:

MEXSOL G K2 Bi22 a MEXSOL G K4 Bi22

are used as dialysis solutions for continuous venous to venous haemodialysis (CVVHD) and for continuous veno-venous hemodiafiltration (CVVHDF) with citrate anticoagulation of 0.5 % with a solution of sodium citrate and with concurrent administration of calcium.

Sterile medical devices containing calcium in variants and with trade names:

MEXSOL H K0 Bi35/ Bicarbonate H K0 Bi35

MEXSOL H K0 Bi35 Mg+/ Bicarbonate H K0 Bi35 Mg+

MEXSOL H K1 Bi35/ Bicarbonate H K1 Bi35

MEXSOL H K1,5 Bi35/ Bicarbonate H K1,5 Bi35

MEXSOL H K2 Bi35/ Bicarbonate H K2 Bi35

MEXSOL H K2 Bi35 Mg+/ Bicarbonate H K2 Bi35 Mg+

MEXSOL H K4 Bi35/ Bicarbonate H K4 Bi35

MEXSOL H K4 Bi35 Mg+/ Bicarbonate H K4 Bi35 M+

are used as dialysis solutions for treatment by renal replacement therapy (RRT).

Sterile medical devices containing calcium in variants and with trade names:

MEXSOL H K1 L40/ Lactate H K1 L40

MEXSOL H K1,5 L40/ Lactate H K1,5 L40

MEXSOL H K2 L40/ Lactate H K2 L40

MEXSOL H K2 L40 Mg+/ Lactate H K2 L40 Mg+

MEXSOL H K1 L45/ Lactate H K1 L45

MEXSOL H K1,5 L45/ Lactate H K1,5 L45

MEXSOL H K2 L45 / Lactate H K2 L45

are used as dialysis solutions for treatment by renal replacement therapy (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 31/12/2028) according to Annex II of the Council Directive 93/42/EEC.

Appendix "A" to EC compliance declaration:**Variants and trade names of calcium-free medical devices with the presence of bicarbonate:**

Trade name	REF
MEXSOL K0 Bi15	701550
MEXSOL K0 Bi20	702050
MEXSOL K2 Bi15	721550
MEXSOL K2 Bi20	722050
MEXSOL K4 Bi15	741550
MEXSOL K4 Bi20	742050
MEXSOL G K2 Bi22	722250
MEXSOL G K4 Bi22	742250
MEXSOL K2 Bi20 P0	722052
MEXSOL K2 Bi20 P0	722060
MEXSOL K2 Bi20 P0	722061
MEXSOL K4 Bi20 P0	742052
MEXSOL K4 Bi20 P0	742060
MEXSOL K4 Bi20 P0	742061
MEXSOL K2 Bi20 P+	722054
MEXSOL K2 Bi20 P+	722057
MEXSOL K2 Bi20 P+	722059
MEXSOL K4 Bi20 P+	742054
MEXSOL K4 Bi20 P+	742057
MEXSOL K4 Bi20 P+	742059

Variants and trade names of medical devices with the presence of calcium and bicarbonate:

Trade name	REF
MEXSOL H K0 Bi35	703560
MEXSOL H K0 Bi35 Mg+	703561
MEXSOL H K1 Bi35	713560
MEXSOL H K1,5 Bi35	763560
MEXSOL H K2 Bi35	723560
MEXSOL H K2 Bi35 Mg+	723561
MEXSOL H K4 Bi35	743560
MEXSOL H K4 Bi35 Mg+	743561

Trade name	REF
Bicarbonate H K0 Bi35	703570
Bicarbonate H K0 Bi35 Mg+	703571
Bicarbonate H K1 Bi35	713570
Bicarbonate H K1,5 Bi35	763570
Bicarbonate H K2 Bi35	723570
Bicarbonate H K2 Bi35 Mg+	723571
Bicarbonate H K4 Bi35	743570
Bicarbonate H K4 Bi35 Mg+	743571

Variants and trade names of medical devices with the presence of calcium and lactates:

Trade name	REF
MEXSOL H K1 L40	714060
MEXSOL H K1,5 L40	764060
MEXSOL H K2 L40	724060
MEXSOL H K2 L40 Mg+	724061
MEXSOL H K1 L45	714560
MEXSOL H K1,5 L45	764560
MEXSOL H K2 L45	724560

Trade name	REF
Lactate H K1 L40	714070
Lactate H K1,5 L40	764070
Lactate H K2 L40	724070
Lactate H K2 L40 Mg+	724071
Lactate H K1 L45	714570
Lactate H K1,5 L45	764570
Lactate H K2 L45	724570

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/3 dated: 1.4.2023