



Notified Body 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

EC Certificate - Full Quality Assurance System No. 19 0664 QS/NB

The quality system of manufacturer

MEDITES PHARMA, spol. s r.o.

1. máje 2625, 756 61 Rožnov pod Radhoštěm, Czech Republic

has been certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II excluding (4)

for the following product category(ies):

Sterile hemodialysis solutions

The Notified Body No. 1023 declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subjected to periodical surveillance. For placing on the market of Class III devices covered by this certificate, an EC Design-Examination Certificate according to Annex II (Section 4) is required.

Valid from: 2021-05-04

Valid until: 2024-05-27

First Issued: 2019-12-10

Revision: d



Date: 2021-05-04

Mgr. Jiří Heš
Representative of the Notified Body No. 1023



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Annex to EC Certificate No. 19 0664 QS/NB

issued for manufacturer:

MEDITES PHARMA, spol. s r.o.

1. máje 2625, 756 61 Rožnov pod Radhoštěm, Czech Republic

Product(s):

Name:

CITRASOL

Trade name(s):

CITRASOL 4% (Natrii citras 4%)

CITRASOL 0.5% (Natrii citras 0.5%)

CITRASOL ACD-A

CITRASOL CPD50

Model(s):

REF 601030 (CITRASOL 4%, volume 250 ml)

REF 601031 (CITRASOL 4%, volume 250 ml)

REF 601010 (CITRASOL 4%, volume 1000 ml)

REF 601011 (CITRASOL 4%, volume 1000 ml)

REF 601510 (CITRASOL 4%, volume 1500 ml)

REF 601023 (CITRASOL 4%, volume 2000 ml)

REF 601021 (CITRASOL 4%, volume 2000 ml)

REF 603050 (CITRASOL 0.5%, volume 5000 ml)

REF 604030 (CITRASOL ACD-A, volume 250 ml)

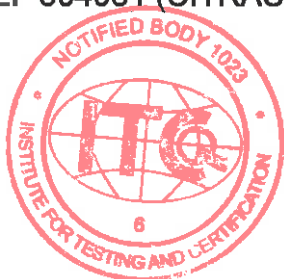
REF 604031 (CITRASOL ACD-A, volume 250 ml)

REF 604050 (CITRASOL ACD-A, volume 500 ml)

REF 604051 (CITRASOL ACD-A volume 500 ml)

REF 604080 (CITRASOL ACD-A volume 750 ml)

REF 604081 (CITRASOL ACD-A, volume 750 ml)



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REF 605020 (CITRASOL CPD50, volume 150 ml)
REF 605021 (CITRASOL CPD50, volume 150 ml)
REF 605030 (CITRASOL CPD50, volume 250 ml)
REF 605031 (CITRASOL CPD50, volume 250 ml)

Class:
GMDN:

IIb
45815



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1. máje 2625, 756 61 Rožnov pod Radhoštěm, Czech Republic

Name: MEXSOL

Trade name(s): MEXSOL

Model(s): K0 Bi15 (REF 701550, volume 4500+500 ml)
K0 Bi20 (REF 702050, volume 4500+500 ml)
K2 Bi15 (REF 721550, volume 4500+500 ml)
K2 Bi20 (REF 722050 volume 4500+500 ml)
K4 Bi15 (REF 741550, volume 4500+500 ml)
K4 Bi20 (REF 742050, volume 4500+500 ml)
K2 Bi20 P0 (REF 722052 / 722060 / 722061, volume 4500+500 ml)
K4 Bi20 P0 (REF 742052 / 742060 / 742061, volume 4500+500 ml)
K2 Bi20 P+ (REF 722054 / 7222057 / 722059, volume 4500+500 ml)
K4 Bi20 P+ (REF 742054 / 742057 / 742059, volume 4500+500 ml)

Class: IIb

GMDN: 35849



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issued for manufacturer:

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1. máje 2625, 756 61 Rožnov pod Radhoštěm, Czech Republic

Name: MEXSOL G
Trade name(s): MEXSOL G
Model(s): K2 Bi22 (REF 722250, volume 4500+500 ml)
K4 Bi22 (REF 742250, volume 4500+500 ml)
Class: IIb
GMDN: 35849

Name: Bicarbonate H
Trade name(s): Bicarbonate H
Model(s): K0 Bi35 (REF 703570, volume 4500+500 ml)
K0 Bi35 Mg+ (REF 703571, volume 4500+500 ml)
K1 Bi35 (REF 713570, volume 4500+500 ml)
K1,5 Bi35 (REF 763570, volume 4500+500 ml)
K2 Bi35 (REF 723570, volume 4500+500 ml)
K2 Bi35 Mg+ (REF 723571, volume 4500+500 ml)
K4 Bi35 (REF 743570, volume 4500+500 ml)
K4 Bi35 Mg+ (REF 743571, volume 4500+500 ml)
Class: IIb
GMDN: 35849



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| | |
|-----------------------|---|
| Name: | MEXSOL H |
| Trade name(s): | MEXSOL H |
| Model(s): | K0 Bi35 (REF 703560, volume 4500+500 ml) K0 Bi35 Mg+ (REF 703561, volume 4500+500 ml) K1 Bi35 (REF 713560, volume 4500+500 ml) K1,5 Bi35 (REF 763560, volume 4500+500 ml) K2 Bi35 (REF 723560, volume 4500+500 ml) K2 Bi35 Mg+ (REF 723561, volume 4500+500 ml) K4 Bi35 (REF 743560, volume 4500+500 ml) K4 Bi35 Mg+ (REF 743561, volume 4500+500 ml) K1 L40 (REF 714060, volume 5000 ml) K1,5 L40 (REF 764060, volume 5000 ml) K2 L40 (REF 724060, volume 5000 ml) K2 L40 Mg+ (REF 724061, volume 5000 ml) K1 L45 (REF 714560, volume 5000 ml) K1,5 L45 (REF 764560, volume 5000 ml) K2 L45 (REF 724560, volume 5000 ml) |
| Class: | IIb |
| GMDN: | 35849 |



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Name: Lactate H
Trade name(s): Lactate H
Model(s): K1 L40 (REF 714070, objem vaku 5000 ml)
K1,5 L40 (REF 764070, volume 5000 ml)
K2 L40 (REF 724070, volume 5000 ml)
K2 L40 Mg+ (REF 724071, volume 5000 ml)
K1 L45 (REF 714570, volume 5000 ml)
K1,5 L45 (REF 764570, volume 5000 ml)
K2 L45 (REF 724570, volume 5000 ml)
Class: IIb
GMDN: 35849

Name: LACSOL
Trade name(s): LACSOL
Model(s): 40-107 (REF 541131, volume 5000 ml)
45-100 (REF 541133, volume 5000 ml)
45-101 (REF 541134, volume 5000 ml)
Class: IIb
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| | |
|-----------------------|--|
| Name: | BICSOL |
| Trade name(s): | BICSOL |
| Model(s): | 35-110 (REF 723550, volume 4500+500 ml) 35-108 K0 (REF 703550, volume 4500+500 ml) 35-112 K4 (REF 743550, volume 4500+500 ml) |
| Class: | Ib |
| GMDN: | 35849 |



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Facility(ies):

MEDITES PHARMA, spol. s r.o.

1. máje 2625, 756 61 Rožnov pod Radhoštěm, Czech Republic

IMUNA PHARM, a.s.

Jarková 269/17, Šarišské Michaľany, Slovak Republic

Haemopharm Biofluids S.r.l.

Via dell'Industria, 6 23030 Tovo di S. Agata (SO), Italy



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Certificate History:

| Revision | Date | Reference Number | Action |
|----------|------------|------------------|---|
| | 2019-12-10 | 803602826 | Recertification process – conformity assessment of CITRASOL |
| a | 2020-03-17 | 803602826 | Recertification process – conformity assessment of MEXSOL, MEXSOL G, MEXSOL H, Lactate H, Bicarbonate H, LACSOL, BICSOL |
| b | 2020-06-02 | 803602852 | Correction of typing error, products LACSOL and CITRASOL |
| c | 2020-10-13 | 803602860 | Addition of new product models CITRASOL ACD-A and CITRASOL CPD50 |
| d | 2021-05-04 | 803602906 | Addition of new product model CITRASOL 4% (REF 601510) |



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