



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. 16 0526 QS/NB

The quality system of manufacturer

**Biomedica, spol. s r.o.**

**Pekařská 8, 155 00 Praha 5, 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):

**Citrate anticoagulation solution  
Hemodialysis concentrate**

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:** 2021-05-11  
**Valid until:** 2024-05-27  
**First Issued:** 2016-11-22  
**Revision:** i



Date: 2021-05-11

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



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

## Annex to EC Certificate No. 16 526 QS/NB

issued for manufacturer:

**Biomedica, spol. s r.o.**  
**Pekařská 8, 155 00 Praha 5, Czech Republic**

### Product(s):

**Name:** **Natrium Citricum 0,5%**

**Trade name(s):** -

**Model(s):** PP 5000 ml

**Class:** IIb

**GMDN:** 45815

**Name:** **Natrium Citricum 4%**

**Trade name(s):** -

**Model(s):** PP bag 250 ml, 1000 ml, 1500 ml, 2000 ml  
PVC bag 250 ml  
LDPE bottle 250 ml

**Class:** IIb

**GMDN:** 45815

**Name:** **Natrium Citricum 14,7%**

**Trade name(s):** -

**Model(s):** PP bag 500 ml

**Class:** IIb

**GMDN:** 45815

Date: 2021-05-11  
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## Annex to EC Certificate No. 16 526 QS/NB

issued for manufacturer:

**Biomedica, spol. s r.o.**  
**Pekařská 8, 155 00 Praha 5, Czech Republic**

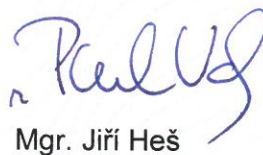
**Name:** **Natrium Citricum 35,3% (1,2 M)**  
**Trade name(s):** -  
**Model(s):** PP bag 250 ml  
**Class:** IIb  
**GMDN:** 45815

**Name:** **Lactocitrate®**  
**Trade name(s):** -  
**Model(s):** PP bag 5000 ml  
**Class:** IIb  
**GMDN:** 45815

**Name:** **Citralysat K2**  
**Trade name(s):** -  
**Model(s):** PP bag 5000 ml  
SA (Sealed Air M312) bag 5000 ml  
**Class:** IIb  
**GMDN:** 35849

Date: 2021-05-11  
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issued for manufacturer:

**Biomedica, spol. s r.o.**  
**Pekařská 8, 155 00 Praha 5, Czech Republic**

**Name:** Citralysat K4  
**Trade name(s):** -  
**Model(s):** PP bag 5000 ml  
SA (Sealed Air M312) bag 5000 ml  
**Class:** IIb  
**GMDN:** 35849

**Name:** Citralysat K2 PLUS  
**Trade name(s):** -  
**Model(s):** PP bag 5000 ml  
SA (Sealed Air M312) bag 5000 ml  
**Class:** IIb  
**GMDN:** 35849

**Name:** Citralysat K4 PLUS  
**Trade name(s):** -  
**Model(s):** PP bag 5000 ml  
SA (Sealed Air M312) bag 5000 ml  
**Class:** IIb  
**GMDN:** 35849

Date: 2021-05-11  
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## Annex to EC Certificate No. 16 526 QS/NB

issued for manufacturer:

**Biomedica, spol. s r.o.**  
**Pekařská 8, 155 00 Praha 5, Czech Republic**

**Name:** **Prismalysat 0cal RCA K4**  
**Trade name(s):** -  
**Model(s):** PP bag 5000 ml  
SA (Sealed Air M312) bag 5000 ml  
**Class:** IIb  
**GMDN:** 35849

**Name:** **Prismalysat 1,75cal**  
**Trade name(s):** -  
**Model(s):** PP bag 5000 ml  
SA (Sealed Air M312) bag 5000 ml  
**Class:** IIb  
**GMDN:** 35849

### **Facility(ies):**

Biomedica, spol. s.r.o.

Hořátev 104, 289 12 Sadská, Czech Republic

Masarykova 200, 763 26 Luhačovice, Czech Republic

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## Annex to EC Certificate No. 16 526 QS/NB

issued for manufacturer:

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**Pekařská 8, 155 00 Praha 5, Czech Republic**

### Certificate History:

Revision	Date	Reference Number	Action
	2016-11-22	803602500	Conformity assessment (recertification)
a	2018-02-06	343603903	Addition of subcontractor's manufacturing site for Citralysat K2
b	2018-04-04	803602672	Conformity assessment (recertification of Citralysat K2 PLUS a Citralysat K4 PLUS)
c	2019-03-29	803602729a	Addition of new models of citrate anticoagulation and hemodialysis solutions; assessment of new packing material; addition of contractual manufactures for Natrium Citricum 4%
d	2019-07-04	803602729b	Assessment of new packaging material (SA) and storage condition concerned to Citralysat K2 / K2 PLUS and Citralysat K4 / K4 PLUS
e	2019-09-12	803602729b	Correction of errors in already issued certificate
f	2020-01-21	803602729c	Addition of new models of hemodialysis concentrates and citrate anticoagulation solution
g	2020-04-21	803602846	Addition of subcontractor's manufacturing site for Natrium Citricum 4% PVC bag 250 ml -VIOSEER S.A., PARENTERAL SOLUTION INDUSTRY; 9th km National Road Trikala-Larisa, Taxiarches Trikala, 42100, Greece
h	2020-05-05	833600185	Addition of subcontractor's manufacturing site for Natrium Citricum 4% PVC bag 250 ml – Imuna Pharm a.s., Jarková 17, 082 22 Šarišské Michal'any, Slovak Republic
i	2021-05-11	803602858	Re-certification and correction product name Lactocitrate® by adding the ® symbol.

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