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 0132 QS/NB

The quality system of manufacturer

Additional Liability Company «TahatAksi»

Republic of Belarus, 220075, Minsk, Selitskogo str., 7,room 4, office 101

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):

Patient heating system, Devices for warming of blood, blood substitute, liquids and infusion 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: 2019-03-29
Valid until: 2024-03-28
First Issued: 2019-03-29
Revision: -

Digitally signed by Levința Alexandru
Date: 2023.06.29 15:12:04 EEST
Reason: MoldSign Signature
Location: Moldova

Date: 2019-03-29

NOTIFIED BODY 1023 · INSTITUTE FOR TESTING AND CERTIFICATION

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. 19 0132 QS/NB

issued for manufacturer:

Additional Liability Company «TahatAksi»
Republic of Belarus, 220075, Minsk, Selitskogo str., 7,room 4, office 101

Product(s):

Name:	**Patient heating systems "Ramonak"**
Trade name(s):	Patient heating systems "Ramonak"
Model(s):	Newborn warming system with water/gel mattress "Ramonak-01"
	Patient warming system with gel pad "Ramonak-03"
Class:	IIb
GMDN:	37329
Name:	**Blood, blood substitute and infusion solution warming device «Ampir-01»**
Trade name(s):	Blood, blood substitute and infusion solution warming device «Ampir-01»
Model(s):	Blood, blood substitute and infusion solution warming device «Ampir-01»
	Blood, blood substitute and infusion solution warming device «Ampir-01A»
Class:	IIb
GMDN:	47617

NOTIFIED BODY 1023 ITC INSTITUTE FOR TESTING AND CERTIFICATION

Date: 2019-03-29
Revision: -

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. 19 0132 QS/NB

issued for manufacturer:

Additional Liability Company «TahatAksi»
Republic of Belarus, 220075, Minsk, Selitskogo str., 7,room 4, office 101

Name:	**Complex for warming liquids and infusion solutions "AMPIRmini"**
Trade name(s):	Complex for warming liquids and infusion solutions "AMPIRmini"
Model(s):	Complex for warming liquids and infusion solutions "AMPIRmini" modification 1 Complex for warming liquids and infusion solutions "AMPIRmini" modification 2 Complex for warming liquids and infusion solutions "AMPIRmini" modification 3
Class:	IIb
GMDN:	47617

Facility(ies):

Additional Liability Company «TahatAksi»
Republic of Belarus, 220075, Minsk, Selitskogo str., 7,room 4, office 101

Additional Liability Company «TahatAksi»
Republic of Belarus, 220101, Minsk, Rokossovskogo Avenue, 166, room 1N (production site)

NOTIFIED BODY 1023 INSTITUTE FOR TESTING AND CERTIFICATION

Mgr. Jiří Heš
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Date: 2019-03-29
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Notified Body 1023
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Annex to EC Certificate No. 19 0132 QS/NB

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Certificate History:

Revision	Date	Reference Number	Action
	2019-03-29	803602576	Certification

NOTIFIED BODY 1023 INSTITUTE FOR TESTING AND CERTIFICATION

Date: 2019-03-29
Revision: -

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