Digitally signed by Levința Alexandru
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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: -

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
Representative of the Notified Body No. 1023

Date: 2019-03-29
Revision: -

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

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: -

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

Institute for Testing and Certification
Notified Body NB 1023
trida Tomase Bati 299
Louky, 76302 Zlín
Czech Republic

In Zlín, on May 03, 2024

NB
Reference: 300/1251/2024

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, Institute for Testing and Certification, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 1023 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Additional Liability Company «TahatAksi»
Selitskogo str. 7, room 4, office 101
220075 Minsk
Belarus
SRN Number: BY-MF-000012521

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

Head office
Institut pro testovani a certifikaci, a.s.
trida Tomase Bati 299, Louky, 763 02 Zlin, Czech Republic

Office Svit area, building No.113
trida Tomase Bati 5264
760 01 Zlin, Czech Republic

Company Id.No: 47910381
VAT No: CZ47910381
Registered: KS Brno, RG.B/1002

☎ +420 572 779 922
✉ itc@itczlin.cz
www.itczlin.cz

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body,

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

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Patient heating systems "Ramonak" **Complex for warming liquids and infusion solutions "AMPIRmini"** **Blood, blood substitute and infusion solution warming device "Ampir-01"**	Class IIb	N/A	EC Certificate – Full Quality Assurance System No. 19 0132 QS/NB, issued by NB 1023

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Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/05/03	300/1257/2024	Initial issue

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