«TahatAksi» ALC
Str. Selitskogo,7, placement 4, room №101
220075, Minsk, Republic of Belarus
Production address: Avenue Rokossovskogo, 166, premices 1N
220101, Minsk, Republic of Belarus
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Digitally signed by Levința Alexandru
Date: 2026.04.03 10:18:43 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

EC Declaration of Conformity

According to Annex II (full quality assurance system) of Directive 93/42/EEC

Manufacturer: Additional Liability Company «TahatAksi»
Legal address: 220075, Republic of Belarus, Minsk, Selitskogo str., 7, room 4, office 101.
Production location: Republic of Belarus, 220101, Minsk, Rokossovskogo Avenue, 166, room 1N.
Product name: 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».
Product description: intended for the prevention and treatment of hypothermia and complications caused by it in pre-, intra- and postoperative periods and prevention of these diseases.
Device «Ampir-01» is versatile device with microprocessor control, self-test program, alarms and automatically maintain the desired temperature heat exchangers.

Types: noninvasive devices, active medical devices, active therapeutic device.
Classification acc.to the Directive 93/42/EEC: IIb class according the Rule 9 Annex IX.

Applied directives: MD Directive 93/42/EEC.

Applied harmonized standards:

Designation	Name
EN ISO 9001:2015	Quality management systems — Requirements
EN ISO 13485:2016	Medical devices. Quality management systems. Requirements for regulatory purposes.
EN ISO 14971:2012	Medical devices. Application of risk management to medical devices
EN 60601-1: 2006 /A1: 2013 (IEC 60601-1:2005/A1:2012)	Medical electrical equipment. General requirements for basic safety and essential performance
EN 60601-1-2:2015 (IEC 60601-1-2:2014)	Medical electrical equipment. General requirements for basic safety and essential performance. Collateral standard. Electromagnetic compatibility. Requirements and tests
EN 60601-1-8:2007/A11:2017 (IEC 60601-1-8:2006 /AMD 1:2012)	Medical electrical equipment -- Part 1-8: General requirements for basic safety and essential performance -- Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems

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Notifed Body: 1023
«INSTITUTE FOR TESTING AND CERTIFICATION», a.s., trida Tomase Bati 299, Louky, 763 02 Zlin, Czech Republic, Telefon: +420 577 601 238.

The Quality System conforms to the Certificates with the requirements of the standards EN ISO 9001:2015, EN ISO 13485:2016 regulations and certified by the «INSTITUTE FOR TESTING AND CERTIFICATION» (certificates № 21 0020 SJ date of issue 07.04.2021; № 21 0021 SJ date of issue 07.04.2021).

EU AUTHORIZED REPRESENTATIVE OF THE MANUFACTURER:
"VERSAMEDIKAS" Ltd., LT 03113, str. Kareiviu, 6, Vilnius, Lithuania, Tel.:+37068685493, E-mail: vadim@versamedica.

«MANUFACTURER» here with declares that the above-mentioned device meets all applicable provisions of the EC MD Directive 93/42/EEC. The device blood, blood substitute and infusion solution warming device «Ampir-01» is safe under prescribed and reasonably foreseeable conditions of storage and use.

"MANUFACTURER" has implemented measures assuring that the device of the above mentioned type is safe and fulfill essential requirements of the 93/42/EEC Directive.

"MANUFACTURER" has instituted and keeps up to date a systematic procedure to review experience gained from devices in the post-production phase and to implement appropriate means for any necessary corrective actions. The company undertakes to notify through its Authorized Representative in EU member state the Competent Authority on any malfunction or deterioration in the product characteristics, performance or inadequacy in the instruction for use which might lead to death or serious damage of patient's health as well as on technical or medical reason leading to systematic recall of the product by manufacturer.

If the device is modified without the agreement of the undersigned, this declaration becomes invalid in relation to the modified product.

Minsk, 07.07.2022
Place, Date

Director **Shmyk S.D.**

CE 1023