

**Общество с ограниченной ответственностью "Современные  
Инновационные Медицинские Технологии"**

**143981, Московская обл., г.Железнодорожный, ул.Южная, д.1**

**ОГРН 1093123002334**

**ИНН / КПП 3123193358/501201001**

## **EC Declaration of Conformity**

issued in accordance with EC Directive 93/42/EEC relating to Medical Devices

**Manufacturer:** SIMT Ltd.  
Russia, 308007, Belgorod, 84 Khmelnitsky avenue

**Product name:** EDTV oscillometer, Model: EDTV HemoDin, EDTV Sport and EDTV School.

**Product description:** The oscillometers EDTV HemoDin, EDTV Sport and EDTV School are intended for noninvasive automatic express diagnosis of the state of cardiovascular system with the topical visualization. Class II a Medical Device

**Applied directives:** MD Directive 93/42/EEC

**Applied harmonized standards:** DIRECTIVE 93/42/EEC, EN ISO 14971, ISO 13485

„**MANUFACTURER**“ herewith declares that the above-mentioned device meets all applicable provisions of the EC MD Directive 93/42/EEC. The device EDTV oscillometers are safe under prescribed and reasonably foreseeable conditions of storage and use.

„**MANUFACTURER**“ has implemented measures assuring that the EDTV of the above mentioned type is safe and fulfills the 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.

**Date of issue: 24<sup>th</sup> October 2012**



  
General Director  
Beloglazova I. Tatyana