ONAYLANMIŞ KURULUŞ 2195
SZUTEST

CE
2195

EC CERTIFICATE

According to Annex II of the Directive 93/42/EEC on Medical Devices

Full Quality Assurance System

Certificate Number: 2195-MED-1325201

Manufacturer:	**ALFA-MED LLC** 34, Shabolovka, Moscow, 115419, Russia
Product(s):	**Active Diagnostic Device For Non-Vital Physiological Parameters**
Type(s)/Model(s):	535, 530, 130, 135
Brand Name(s):	SENSITIV IMAGO
Final Report No:	2195-MED-1309001

Szutest, Notified Body 2195, declares that the aforementioned manufacturer has implemented a quality assurance system according to Annex II, Section 3 of the directive 93/42/EEC on medical devices. This quality assurance system covers those aspects of manufacturing concerned with securing and maintaining safe conditions of the respective product(s) and conforms to the provisions of this Directive. The approved quality system is subject to surveillance pursuant to Annex II, Section 5 of Directive 93/42/EEC.

Szutest must be informed of any significant changes in the design and/or construction of the product(s).

İstanbul, 2013-09-09

SZUTEST TEKNİK KONTROL VE BELGELENDİRME HİZM. TİC. LTD. ŞTİ. ONAYLANMIŞ KURULUŞ 2195

Mehmet IŞIKLAR
General Manager

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