

# ELEKTROTECHNICKÝ ZKUŠEBNÍ ÚSTAV



ELECTROTECHNICAL TESTING INSTITUTE - CZECH REPUBLIC  
ELEKTROTECHNISCHE PRÜFANSTALT - TSCHECHISCHE REPUBLIK  
INSTITUT ELECTROTECHNIQUE D'ESSAIS - RÉPUBLIQUE TCHÉQUE  
ЭЛЕКТРОТЕХНИЧЕСКИЙ ИСПЫТАТЕЛЬНЫЙ ИНСТИТУТ - ЧЕШСКАЯ РЕСПУБЛИКА

Pod Lisem 129, 171 02 Praha 8 - Troja

## CE - CERTIFICATE

of full quality assurance system

No.: MED 110018

The Electrotechnical Testing Institute, Notified Body No. 1014, has decided that Quality System applied by

manufacturer **2 ES, spol. s r.o.**  
**Pantočková 90, 38001 Dačice IV, Czech Republic**

in manufacturing sites **2 ES, spol. s r.o.**  
**Masarykova 350, 394 70 Kamenice nad Lipou, Czech Republic**

for design, manufacture and final inspection of medical devices

**Medical devices class IIa: Infrared pad type IR 10 M, Polarized light type BL 43 M, Polarized light Solaris**

complies with provisions of Annex 2 section 3 of Governmental Order No. 336/2004 Coll. (Annex II section 3 of the Council Directive 93/42/EEC) incl. amendments.

This decision is based on the results presented in report No. 100233-03 of: 20.01.2011,  
105496-01 of: 26.01.2012,  
203482-01/02 of: 06.09.2012

In accordance with Art. 5 of Governmental Order No. 336/2004 Coll. (Art. 17 of Directive 93/42/EEC), incl. amendments the above specified medical device must be labelled CE 1014.

The certified manufacturer is subject to a surveillance audit by the notified body in accordance with section 5 of Annex 2 of Governmental Order No. 336/2004 Coll. (Annex II section 5 of Directive 93/42/EEC) incl. amendments, and validity of the Certificate is subject to regular supervision. The manufacturer must inform the notified body about any intention resulting in significant modification of quality system or scope of included medical products. In the event that the conditions under which the Certificate has been issued are violated, the notified body may suspend the Certificate's validity or cancel the Certificate.

Edition 1

Date of first issue of Certificate with validity until  
**The validity of current Certificate is limited until: 31.1.2016**

20.2.2012 extension 12.9.2012

Prague

  
Miroslav Sedláček  
Certification and Inspection Manager



Stamp



100233-03