

ELEKTROTECHNICKÝ ZKUŠEBNÍ ÚSTAV



ELECTROTECHNICAL TESTING INSTITUTE - CZECH REPUBLIC
ELEKTROTECHNISCHE PRÜFANSTALT - TSCHHECHISCHE 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 070036

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

manufacturer

A.I.P. DEVELOPPEMENT S.A.
Rue Des Artisans, 2 B-4877, OLNE, Belgium

for design, manufacture and final inspection of medical devices

Practisteel stainless steel wire non-absorbable surgical suture - class IIb
Non-absorbable surgical sutures and accessories, Absorbable surgical sutures, Absorbable haemostat-class III

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. 701340-04 of: 28.12.2013

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: 28.5.2018

21.01.2014 corrigendum 03.12.2015

Prague


Miroslav Sedláček
Certification and Inspection Manager



Stamp



701340-04