Notified Body No. 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.
Zlin, Czech Republic – www.itczlin.cz

EC CERTIFICATE

No. 11 0282 QS/NB/a

issued in compliance with the Council Directive 93/42/EEC as amended, which is implemented by the Czech Government Order No. 336/2004 as amended (Collection of Laws), certifies that the products – medical devices of Class IIa,

Disposable Medical Products:

Sterile Guidewire for single use, Sterile Introducer Tool Kit for Single Use, Seldinger Needle, Intervention Accessories Kit for Single Use (including Introducer Set, Y-Connector Pack, manifolds, angiography syringe, seldinger needle, inflation device and pressure monitoring tube)

manufactured by company

ARES MEDIKAL SANAYI TICARET LIMITED SIRKETI
ASIK VEYSEL MAHALLESI 5821/1 SOK. NO:6 KARABAGLAR, IZMIR, TURKEY

are manufactured under conditions fulfilling the quality system requirements of Annex II, Section 3.2. of the Directive 93/42/EEC, as amended.

The Notified Body No. 1023 has performed an audit of the above products quality system covering the design, manufacture and final inspection of the certified products. The quality system has been assessed, approved and is subject to continuous surveillance according to Annex II, Sections 3.3. and 5., of the Directive 93/42/EEC. The detailed description of the system parts, requirements and measures applied by the manufacturer are presented in the Final Report No. 803601163/2011 and 343601865/2014 which is enclosed to this Certificate.

Condition of this Certificate use and related information:

1. *It applies only to the quality system maintained in the manufacture of above referenced models of medical devices and it does not substitute the design or type-examination procedures, if requested.*
2. *The Certificate remains valid until the manufacturing conditions or the quality system are changed but until the **12th February 2019** at the latest.*
3. *The Certificate validity is conditioned by positive results of surveillance audits.*
4. *After fulfilling the relevant EU legislation, the manufacturer shall affix to each medical device, of the above referenced models, the CE-marking followed by the number of the Notified Body according to this example:*

CE 1023

INSTITUTE FOR TESTING AND CERTIFICATION 1023 NOTIFIED BODY

RNDr. Radomír Čevelík
Representative of the Notified Body No. 1023

Issued in Zlín, on 26th March 2014
Replaces the withdrawn EC Certificate No. 11 0282 QS/NB issued on 11th April 2011