



Notified Body No 1023  
**INSTITUTE FOR TESTING AND CERTIFICATION, Inc.**  
Zlín, Czech Republic – [www.itczlin.cz](http://www.itczlin.cz)

# EC CERTIFICATE

**No. 10 0664 QS/NB/b**

issued in compliance with the Council Directive 93/42/EEC as amended, which is implemented by the Czech Government Order No. 54/2015 (Collection of Laws), certifies that the products – medical devices of Class IIb

## **Mesh for Hernia Mesh for Incontinence**

manufactured by company

**Klas Medikal Cihazlar Sanayi Mumessillik Ic ve Dis Tic Ltd. Sti.**  
**Ramazanoğlu Mahallesi Yıldırım Sokak. No:1 Pendik 34906, İstanbul, 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 product 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 Reports No. 803600902a/2010, No. 343602841/2014 and No. 343603256/2015, which are 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 9<sup>th</sup> August 2017 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**



*Paul Vaj*  
RNDr. Radomír Čevelík

Issued in Zlín, on 30<sup>th</sup> June 2015

Replaces withdrawn EC Certificate No. 10 0664 QS/NB/a issued on 16<sup>th</sup> July 2014

Representative of the Notified Body No. 1023

## ATTESTATION CE / EC CERTIFICATE

Approbation du Système Complet d'assurance Qualité / Approval of full Quality Assurance System

**ANNEXE II excluant le point 4 Directive 93/42/CEE relative aux dispositifs médicaux**

*ANNEX II excluding section 4 Directive 93/42/EEC concerning medical devices*

**Pour les dispositifs de classe III, un certificat CE de conception est requis**

*For class III devices, a EC design certificate is required*

Fabricant / Manufacturer

**ASPIDE MEDICAL**

**246 allée Lavoisier**

**42350 LA TALAUDIÈRE FRANCE**

Catégorie du(des) dispositif(s) / Device(s) category

**Implants de renfort et de soutènement, à base de polymère ou de silicone, pour les chirurgies générale et plastique, viscérale et digestive, gynécologique et urologique, et ancillaires associés.**  
**Instruments pour les chirurgies générale et plastique, viscérale et digestive, gynécologique et urologique.**

*Reinforcement and support implants, polymer or silicone based, for general and plastic, visceral and digestive, gynecological and urological surgeries, and associated ancillaries.*  
*Instruments for general and plastic, visceral and digestive, gynecological and urological surgeries.*

Voir détails sur addendum / See attachment for additional information

Le LNE/G-MED atteste qu'à l'examen des résultats figurant dans le rapport référencé N090171-R, le système d'assurance qualité - pour la conception, la production et le contrôle final - des dispositifs médicaux énumérés ci-dessus est conforme aux exigences de l'annexe II excluant le point 4 de la Directive 93/42/CEE.

*LNE/G-MED certifies that, on the basis of the results contained in the file referenced N090171-R, the quality system - for design, manufacturing, and final inspection - of medical devices listed here above complies with the requirements of the Directive 93/42/EEC, annex II excluding section 4*

La validité du présent certificat est soumise à une vérification périodique ou imprévue  
The validity of the certificate is subject to periodic or unexpected verification

Début de validité / Effective date : **June 5th, 2013 (included)**

Valable jusqu'au / Expiry date : **June 4th, 2016 (included)**



For the General Director  
**Laurence DAGALLIER**  
Deputy Director