



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

# EC CERTIFICATE

**No. 12 0278 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 (Collection of Laws), certifies that the product – medical device of Class IIb:

## **HIFU Machine**

**Brand names: HTA' ULTRA FACE; HTA' ULTRA FACE-PLUS**

manufactured by company

## **HIGH TECH AESTHETIC**

**41 Avenue Félix Faure – 26000 Valence – FRANCE**

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

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. 803601400/2012 and 803601559/2012, 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 the 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 27<sup>th</sup> February 2022 at the latest.*
3. *The Certificate validity is conditioned by positive results of surveillance audits.*
4. *After fulfilling the relevant EU legislation requirements, 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**



*R. Radomír Čevelík*

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

Issued in Zlín, on 24<sup>th</sup> Feb 2017

Replaces the withdrawn EC Certificate No. 12 0278 QS/NB issued on 27<sup>th</sup> June 2012