



Notified Body 1023  
**INSTITUTE FOR TESTING AND CERTIFICATION, Inc.**,  
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

## EC Certificate - Production Quality Assurance No. 18 0591 QS/NB

The quality system of manufacturer

**ZES Brno, a.s.**

**Sladovnická 518/4, 62000 Brno, Czech Republic**

has been certified as meeting the requirements of

**Directive 93/42/EEC**

**on medical devices, Annex V**

for the following product category(ies):

**Portable magnetotherapeutic devices Renaissance®**

The Notified Body No. 1023 declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. This quality assurance system conforms to the requirements of this Directive and is subjected to periodical surveillance. For placing on the market of Class IIb and Class III devices covered by this certificate, an EC Type-Examination Certificate according to MDD Annex III is required.

**Valid from:** 2018-11-29  
**Valid until:** 2023-11-28  
**First Issued:** 2018-11-29  
**Revision:** -



Date: 2018-11-29

**Mgr. Jiří Heš**  
Representative of the Notified Body No. 1023



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INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,  
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

## Annex to EC Certificate No. 18 0591 QS/NB

issued for manufacturer:

**ZES Brno, a.s.**  
**Sladovnická 518/4, 62000 Brno, Czech Republic**

### Product(s):

**Name:** Portable magnetotherapeutic devices  
**Renaissance®**

**Trade name(s):** Portable magnetotherapeutic device Renaissance® with  
applicators and pulse generator Duo Comfort  
Portable magnetotherapeutic device Renaissance® with  
applicators and pulse generator Duo Forte

**Model(s):** Portable magnetotherapeutic device Renaissance® with  
applicators and pulse generator Duo Comfort  
Portable magnetotherapeutic device Renaissance® with  
applicators and pulse generator Duo Forte

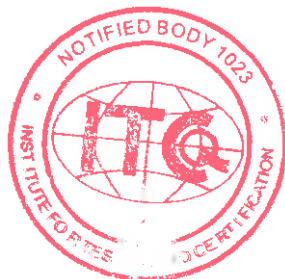
**Applicators:** Manic, Piano, Becco, Lettino, Casso, Cavo, Viera

**Class:** IIa

**GMDN:** 58761

### Facility(ies):

ZES Brno, a.s.  
Sladovnická 518/4, 62000 Brno, Czech Republic



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**Certificate History:**

Revision	Date	Reference Number	Action
	2018-11-29	803602606	Certification



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