

ES DECLARATION OF CONFORMITY

FOR HEALTH APPLICATION
(NV č. 336/2004 Coll. Appendix 5)

Manufacturer:

ZES Brno, a.s.
Sladovnická 4, č.p. 518
620 00 Brno
Czech Republic

Identification No of the organisation: 49969510

Produkt:

Magneto-therapeutic Medical Device **RENAISSANCE**®

Model:

Pulse Generators: R2000, R2010, RENAISSANCE DUO, RENAISSANCE DUO COMFORT,
Magnetic Field Applicators: Piego, Manic, Becco, Piano, Lettino, Causo, Cavo, Fulmio
Power Adapter: VADSBO, 230VAC/12VAC 20VA

Description:

Medical appliance – magnetotherapeutic instrument with applicators instrument supply 230V ~ , 50 Hz, max. 20 W

Use:

A medical instrument designed for the application of low frequency magnetic fields

Classification class:

IIa

List of technical regulations and standards used in the assessment of conformity:

- 336/2004 Coll. Appendix 5
- CSN EN 60601-1:94+A1, A11, A12:95+A2, A13:97
- CSN EN 60601-1-2:03
- CSN EN ISO 13485:03
- CSN EN 10993-1
- Clinic assessment no. KZ/1106/2005/Ro – FN Brno

Notified entity:

The Engineering Testing Institute, Brno, Czech Republic
Notified entity no. 1015, reg. no.: 0001490

Certificate No.:

CQS 113/2006, E-31-00149-05, E-31-00289-06
The Engineering Test Institute, Brno, Czech Republic
Notified entity no.1015, reg. no.: 0001490

The manufacturer declares that:

- Product conformity assessment has been performed in accordance with Section 12 of Act 22/1997 Coll. in the sordiny of later amendments and supplements and accordance with government decree 336/2004 Coll. (guideline 93/42/EHS)
- This medical appliance is safe for use its normal purpose under normal conditions
- This medical appliance is designed for repeated use under the stipulaed hygiene conditions

Issued in: Brno

Date od issue:
1.7.2011

NAME: Mgr. Zuzana Resslerová
Position: Centre Director
Signature:

Mgr. Zuzana Resslerová



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