



EC DECLARATION OF CONFORMITY 4/EN

The undersigned, Tomasz Jakubik and Rafał Mazurek, proprietors of EMED

Adres: Ul. Ryżowa 69A, 05-816 Opacz k/Warszawy

phone (+48 22) 723-08-00, fax (+48 22) 723-00-81

herewith declares that the products range

ELECTROSURGERY UNIT

(ES 120/300/350/400/ES Argon/ES350 with argon beamer/ES350 with argon beamer and ThermoStapler Range)

Medical Products Class IIb (Annex 9, rules 6, 7 & 9)

is in conformity with the Essential Requirements and provisions of the Council Directive 93/42/ EEC - Medical Devices and that the standard referenced below have been applied:

- > EN IEC 60601-1:1990 *Medical electrical equipment-Part 1: General requirements for safety – IEC 601-1:1988*
- > EN IEC 60601-2 -2:1998 *Medical electrical equipment-Part 2-2: Particular requirements for the safety of high frequency surgical equipment – IEC 601-2-2:1991*
- > EN IEC 60601-1-2:2001 *Medical equipment; Part 1: General Requirements for safety; 2. Collateral standard: electromagnetic compatibility; requirements and tests*

is subject to the procedure set out in Annex 2 of Directive 93/42/EEC (except clause 4); EMED have established Full Quality Assurance System certified to ISO 9001/EN 13 485 and under surveillance by:

**Notified Body Number 1011,
Institute for Medical and Hospital Engineering (ORKI)
Diós árok 3, H-1125 Budapest 114, HUNGARY**

Above declaration is valid for generators ES300/350/400/ES350 with argon beamer marked by serial nos from 30350 to 30550, from 35300 to 36500, from 40100 to 40300.

CE 1011

Place.....Warszawa.....

Date.....2005-11-11.....

Signatures.....

Tomasz Jakubik

Rafał Mazurek

EMED T. Jakubik, R. Mazurek
Ul. Ryżowa 69A
05-816 Opacz
tel. (+48 22) 723 08 00
fax (+48 22) 723 00 81



Declaration of compatibility


We EMED T. Jakubik, R. Mazurek, the producer of electrosurgical units:

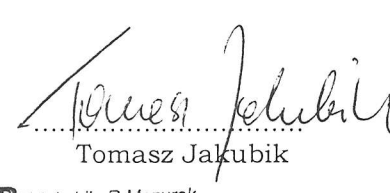
ES120/ES300/ES350/ES350 Argon/ES400/ES ARGON/ES VISION

hereby confirm in sole of responsibility that the following medical products produced by BOWA-electronic GmbH, Nehrener Str. 4-6, D-72810 Gomaringen, Germany are compatible with our electrosurgical units.

Product description	Product No.
Monopolar and bipolar cables for electrosurgery	100-xxx to 410-xxx
Monopolar and bipolar adaptors	111-xxx to 901-xxx
Reusable return plates	193-xxx, 242-xxx, 232-xxx
Monopolar standard electrodes	500-xxx, 530-xxx
Monopolar extended electrodes	520-xxx, 530-xxx
Monopolar arthroscopic electrodes	510-1xx
Bipolar forceps	605-xxx
Monopolar forceps	610-xxx
LAP electrodes	700-xxx, 710-xxx
Electrosurgical handles	10x-xxx, 2xx-xxx, 3xx-xxx, 4xx-xxx, 932-041
Electrode containers	5xx-xxx
Single-use pencils	80x-030
Single-use return plates	81x-xxx
Single-use bipolar forceps	82x-001
Rubber band for return plates	194-xxx
Argon coagulation electrodes	932-xxx
Bipolar endoscopic instruments	75x-xxx
Monopolar endoscopic instruments	72x, 736-005, 743-005

Opacz, 2005-08-08


Rafał Mazurek


Tomasz Jakubik

EMED T. Jakubik, R. Mazurek
05-816 OPACZ, ul. Ryżowa 69A
NIP 527-199-66-17, Regon 010949914
Tel. (22)723 0 800, Fax (22)723 00 81