

## Medical Evaluation, Confirmation Medical Device Dr. Andreas Marx – ClevaMed, Sept. 20th, 2007

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EG-Instruction 93/42 EWG und MEDDEV.2.7.1

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Translation of chapter 9 “Summary” of the Clinical Evaluation  
“BabyComp / LadyComp / Pearly” Rev. 01

Clinical Expert: Dr. med. Andreas Marx

### Summary

Valley Electronics GmbH develops and manufactures hand-held electronic fertility indicators for pregnancy prevention and family planning since years. The devices were designed in close cooperation with engineers, technicians, and gynecologists.

The devices under evaluation “Lady-Comp” and “Baby-Comp” are commercially available since many years. The latest model “Pearly” is a less featured and therefore a low-priced version within the product family of electronic fertility computers. However its technology is based on the reliable platform of the established models “Lady-Comp” and “Baby-Comp”.

The high measurement accuracy of the temperature sensors and the precise algorithm of the temperature calculation provide a high degree in method safety, which clearly stands out from competitive devices.

The handling and operation of the device is user friendly and easy; all relevant items which ensure a safe and correct application of the device are described comprehensibly in the instructions for use.

Several scientific investigations, which were published in recognized journals, provide substantial evidence of the contraceptive effectiveness and safety of the VE electronic fertility devices. All investigations and studies were conducted independently; non of the participating physicians received any financial grant nor had a relationship with the manufacturer Valley Electronics, thus allowing to consider the published data as reliable and objective.

The use of the fertility computers from Valley Electronics allows women to apply a contraceptive method which is based on the natural family planning method. The benefit of the devices obviously lies in a safe and adverse event-free method of contraception and family planning.

ClevaMed • Dr. med. Andreas Marx • Beim Hohen Kreuz 31 • D-87727  
Babenhausen  
Telefon +49 (0) 8333 / 93 58 82 • Telefax + 49 (0) 8333 / 94 65 55 •  
amarx@clevamed.com

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computers

LADY-COMP®  
BABY-COMP®  
pearly®



VE Valley Electronics GmbH  
Wengwies 2  
D-82438 Eschenlohe

Tel (+49) 0 88 24 18 31  
Fax (+49) 0 88 24 80 71

www.baby-comp.com  
info@baby-comp.com

www.valley-electronics.com  
info@valley-electronics.com