EC CERTIFICATE

for the Quality Assurance System

according the directive 93/42/EEC, Annex II excluding section (4)

As a notified body of the European Union, DEKRA Certification GmbH certifies, that the company

BIOPTRON AG

Certified location:

Sihleggstraße 23, CH-8832 Wollerau, Switzerland

applies a quality assurance system for the medical devices listed in the annex according to the directive 93/42/EEC annex II. The approval is based on the result of the re-certification audit report no. 50344-Z4-00, the decision dated 17.07.2013 is only valid in connection with the successful performance of the annual surveillance audits.

Date of the first certification: 21.07.1998

Date of the last recertification: 21.07.2013

This certificate is valid until: 20.07.2016

Certificate registration No.: 50344-16-04
Duplicate

DEKRA Certification GmbH
Stuttgart, 17.07.2013
Notified Body ID-number: 0124

DEKRA Certification GmbH • D-70565 Stuttgart, Handwerkstraße 15 • DEKRA

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-295.10.02

Annex to the Certificate 50344-16-04 dated 17.07.2013

Revision status: 0 Date: 21.07.2013 Page 1 of 1

Devices/device categories included in the certificate

Class II a:

light therapy devices

- Bioptron 2 / B2
- Bioptron Compact III / BC III
- Bioptron Pro 1 / BPro1

Indications for use of the Bioptron Light therapy devices:

Wound healing in venous leg ulcers, pressure sores, burns. Pain treatment in Rheumatology, Physiotherapy, sports medicine. Dermatological disorders and skin problems (acne, herpes, psoriasis). Dermal affections in newborns. In Pediatrics-Musculoskeletal and Allergic respiratory disorders, dermal affections. Seasonal affective disorders (mild depressions, sleep disorders, chronic fatigue syndrome).