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

Sihleggstraße 23, 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-Z5-00, the decision dated 2016-07-19 is only valid in connection with the successful performance of the annual surveillance audits.

This certificate is valid from 2016-07-21 to 2019-07-20

Certificate registration No.: 50344-16-05

DEKRA Certification GmbH Stuttgart; 2016-07-19
Notified Body ID-number: 0124

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

Annex to the EC Certificate 50344-16-05 dated 2016-07-19

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

Devices/device categories included in the certificate

Class II a:

Light therapy devices

- Bioptron MedAll
- Bioptron Pro 1 / BPro1
- Bioptron 2 / B2