TÜVRheinland®

EC Certificate

Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60139368 0001

Report No.: 26300448 002

Manufacturer:
Bioptron AG
Sihleggstr. 23
8832 Wollerau
Switzerland

Products: Light therapy devices

(see attachment for site included)

Expiry Date: 2024-02-14

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2019-07-22

Date: 2019-07-22

Notified Body

TÜV Rheinland LGA Products GmbH – TÜVRheinland® – Zertifizierungsstelle

D. Swiatko

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

Digitally signed by Marenic Nicolai
Date: 2023.11.30 15:35:32 EET
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Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60139368 0001
Report No.: 26300448 002

Manufacturer: Bioptron AG
Sihleggstr. 23
8832 Wollerau
Switzerland

Location included:

Bioptron AG
Gouttes d'Or 30
2008 Neuchâtel
Switzerland

Activity: Design and development, manufacture of light therapy devices

Notified Body

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

D. Swiatko

Date: 2019-07-22