

Certificate

Quality Management System EN ISO 13485:2016

Registration No.:

SX 1551297-1

Organization:

Bioptron AG Sihleggstr. 23 8832 Wollerau Switzerland

Scope:

Design and development, production, distribution and servicing

of light therapy devices.

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.

Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 84957403-30
Effective date: 2022-02-15
Expiry date: 2025-02-14
Issue date: 2022-02-14



TÜV Rheinland LGA Products GmbH Tillystraße 2 · 90431 Nürnberg · Germany



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The scope of certification includes the following additional sites:

No.	Facility	Scope
/01	Bioptron AG Sihleggstr. 23 8832 Wollerau Switzerland	Design, development and distribution of light therapy devices.
/02	Bioptron AG Gouttes d'Or 30 2008 Neuchâtel Switzerland	Production, distribution and servicing of light therapy devices.

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