Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*[1]
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	**BIOPTRON AG**
Manufacturer address and contact details	**Sihleggstrasse 23 CH-8832 Wollerau Switzerland**
Single Registration Number (SRN)	**CH-MF-000041313**

Authorised Representative name	MDR Regulator Sp. z o. o.
Authorised Representative address and contact details	Al. Jerozolimskie, 123A 02-017 Warszawa
Single Registration Number (SRN)	PL-AR-000002485

Notified body name	TüV Rheinland LGA Products GmbH
Notified body number	0197
Directive Certificate number(s) to which this confirmation is made	**HD 60139368 0001**
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity	2024-02-14
End date of extended validity/transition period	2028-12-31

We, as the manufacturer declare under our sole responsibility:

MR

BIOPTRON AG
Sihleggstrasse 23, CH-8832 Wollerau
Phone: +41 43 888 28 00 Fax: +41 43 888 28 99
light@bioptron.com | www.bioptron.com
Bank: UBS AG, CH-6900 Lugano
SWIFT: UBSWCHZH80A, BC 247
IBAN CHF: CH94 0024 7247 5714 9301 B
IBAN EUR: CH24 0024 7247 5714 9362 L
IBAN USD: CH57 0024 7247 5714 9361 C

- for the above listed **Directive Certificate** the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*[2]
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.

  Choose applicable statements:

  ☐ Expired *before* 20 March 2023:

  ☐ Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of a device(s) intended to substitute that/those device(s), or

  ☐ A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request), or

  ☐ A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

  Choose one of the following statements only if a derogation per Article 59(1) or a requirement per Article 97(1) has been granted by a Competent Authority:

  ☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

  ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

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☒ Expired/expires *after* 20 March 2023:

Choose one applicable statement:

- ☒ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
- ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Upclassified devices**

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

Choose one applicable statement:

- ☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitutes and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
- ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Quality Management System (QMS)**

Choose one applicable statement:

- ☐ A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.
- ☒ A QMS in accordance with Article 10(9) MDR is in place.
- ☐ A notified body has issued the attached certificate for the MDR-compliant QMS.

➢ **Device(s) as listed in the attached schedule**

- The device(s) continue to comply with the AIMDD or MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

Full Company Name: **BIOPTRON AG**

Location & Date: **Wollerua /27.05.2024**

Signature, Name, **Title Michal Prazmo / Technical Director / PRRC**

Contact Details: **prazmo@bioptron.com**

BIOPTRON AG
Sihleggstrasse 23 CH-8832 Wollerau
Switzerland

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Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s)[3]	Directive Certificate number(s) to which this confirmation is made	Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity	Notified Body name and number that issued the Directive Certificate	Notified Body name and number where the MDR application was lodged/contract signed	End date of extended validity/transition period	Substitute Device(s) (if applicable)
BIOPTRON MedAll (a.k.a MedAll)	HD 60139368 0001	2024-02-14	TüV Rheinland LGA Products GmbH 0197	SGS BELGIUM NV 1639	2028-12-31	N/A
BIOPTRON Pro1 (a.k.a BPro1)	HD 60139368 0001	2024-02-14	TüV Rheinland LGA Products GmbH 0197	SGS BELGIUM NV 1639	2028-12-31	N/A
BIOPTRON 2 (a.k.a B2)	HD 60139368 0001	2024-02-14	TüV Rheinland LGA Products GmbH 0197	SGS BELGIUM NV 1639	2028-12-31	N/A

BIOPTRON LIGHT THERAPY SYSTEMS
BIOPTRON AG
Sihleggstrasse 23 CH-8832 Wollerau
Switzerland

BIOPTRON AG
Sihleggstrasse 23,
8832 Wollerau,
Switzerland

01/06/2024

Confirmation Letter Reference: CLNB1639 - HU/BUD/20148579

To whom it may concern,

Confirmation of receipt of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

This letter confirms that, SGS Belgium NV, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 1639 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer

BIOPTRON AG
Sihleggstrasse 23,
8832 Wollerau,
Switzerland
SRN Number: CH-MF-000041313

MDR Regulator Sp. z o.o. / Katarzyna Wesołowska
Al. Jerozolimskie 123a,
02-017 Warszawa
Poland

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below . Table 1 identifies the devices which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that:

- The manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry;
- The certificates expired after 26th May 2021 by course of time and were valid at the date of their expiry neither having been suspended nor withdrawn.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3 of MDR (as amended by EU 2023/607), are shown below:

- 26th May 2026 for Class III custom-made implantable devices
- 31st December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31st December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31st December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body SGS Belgium NV NB1639,

pp [Jérôme JADOT]

Virginie SILORET
Global Medical Device Certification Manager
Email: Virginie.siloret@sgs.com
Phone: +41 22 739 98 58

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive**:**

Device name or Basic UDI-DI	**MDR Device classification**	**MDD Device name**	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	**MDD/AIMDD Certificate Reference(s)** of the devices under MDR application, and the NB Identification
Basic UDI-DI: 7612675LightTherapyUK BIOPTRON Therapeutic Healing Light System Therapeutic healing light intended for treatment of rheumathology, physiotherapy, dermatology, wound care, sport medicine, 3 variants: B2, BPro1, MedAll	Class IIa	Light Therapy device Bioptron B2, Bioptron Pro1 Bioptron MedAll	N/A	HD 60139368 0001 NB0197

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	**MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)**	**If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device**	**MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification**
N/A all SUR visit performed by SGS	N/A	N/A	N/A

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/06/01	Version 1	Initial issue

Business Stream Products
Certification Department

TÜVRheinland®
LGA
Precisely Right.

TÜV Rheinland LGA Products GmbH • 51105 Köln

Bioptron AG
Sihleggstr. 23
8832 Wollerau
Switzerland

Contact

Tel. +49 911 655-5225
Mail: service
@de.tuv.com

Date May 21, 2024

Application for: QMS
Certificate No. : HD 60139368 0001
Requirement : Directive 93/42/EEX Annex II, excluding Section 4

Dear Madam or Sir,

Please note that the certificate number HD 60139368 0001, issued to Bioptron AG under Directive 93/42/EEC Annex II (excluding Section 4), with an effective date of 2019-07-22 and an expiry date of 2024-02-14, has never been suspended, restricted or withdrawn.

Best regards,

Jarosław Pyclik
Certification body

TÜV Rheinland
LGA Products GmbH

Am Grauen Stein
51105 Köln
Germany

Headquarter

Tillystraße 2
90431 Nuremberg

Phone. +49 911 655 5225
Fax +49 911 655 5226
service@de.tuv.com
www.tuv.com/safety

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

D. Swiatko

TÜV Rheinland LGA Products GmbH - TÜVRheinland® - Zertifizierungsstelle

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.

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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

Certificate

TÜVRheinland®

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 Zertifizierungsstelle

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

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1551297-1

Organization:
Bioptron AG
Sihleggstr. 23
8832 Wollerau
Switzerland

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.

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

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Daniel Swiątko
TÜV Rheinland LGA Products GmbH
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DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02