

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*
- 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 8832 Wollerau Switzerland

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

Notified body name	TÜV Rheinland LGA Products GmbH
Notified body number	Accreditation-No: 0197
Directive Certificate number(s)	HD 60139366 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	2024-05-26

We, as the manufacturer declare under our sole responsibility:

- 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** as listed above

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covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.

Expired/expires *after* 20 March 2023:

- 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.

➤ **Quality Management System (QMS)**

- 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 as listed in the attached schedule**

- The device(s) continue to comply with the 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 **Wollerau; 14.02.2024**

Signature, Print Name, Title: 

Contact Details : prazmo@bioptron.com

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 prior to the extension of the validity	Notified Body name and number that issued the Directive Certificate	End date of extended validity / transition period
BIOPTRON MedAll (PAG-960)	HD 60139366 0001	2024-02-14	TÜV Rheinland LGA Products GmbH	2024-05-26
BIOPTRON Pro1 (PAG-990)	HD 60139366 0001	2024-02-14	TÜV Rheinland LGA Products GmbH	2024-05-26
BIOPTRON B2 (PAG-880)	HD 60139366 0001	2024-02-14	TÜV Rheinland LGA Products GmbH	2024-05-26



Michal Prazmč