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EKU Elektronik GmbH | Am Sportplatz | D-56291 Leiningen

Leiningen, September 30, 2024

Manufacturer's Declaration

Dear Ladies and gentlemen,

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

- the validity of certificates issued under Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) and
- the compliance with the conditions for further placing on the market and putting into service by the devices and us as their manufacturer

Manufacturer:

Manufacturer name	EKU Elektronik GmbH
Manufacturer address and contact details	Am Sportplatz, 56291 Leiningen
Single Registration Number (SRN)	DE-MF-000016972

Directive Certificate:

Notified Body name	mdc medical device certification GmbH
Notified Body number	0483
Registration number	D1033400007
Name/Directive Certificate number to which this confirmation is made	EG-Certificate / P20-00136-168088
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity	2024-05-26
End date of extended validity/transition period	2028-12-31

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We as the manufacturer declare under our sole responsibility:

- that 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
- that the **list of products** in the attached addendum and that 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Directive Certificate covering the **listed products** was issued after 25 May 2017, was valid on 26 May 2021, was not withdrawn by 20 March 2023.

- *The following marked statements apply in our case:*

☐ Directive Certificate expired *before* 20 March 2023:

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

☐ 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)

☐ 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)

☒ Directive Certificate expired/expires *after* 20 March 2023:

☒ A formal application for conformity assessment with the Notified Body in accordance with section 4.3 subparagraph 1 of Annex VII of the MDR has been submitted by us to a Notified Body by May 26, 2024 for the replacement device and a written agreement in accordance with section 4.3 subparagraph 2 of Annex VII of the MDR is signed before September 26, 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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Quality Management System (QMS)

Choose one applicable statement:

☒ A QMS in accordance with Article 10(9) of the MDR has been established until May 26, 2024.

☐ A Notified Body has issued the attached certificate for the MDR-compliant QMS.

The products listed (see the list of products):

- The products continue to comply with the MDD.
- The products have not been significantly changed in their design and intended use since 26 May 2021.
- The products 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:

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Leiningen, September 30, 2024

Matthias Thiele, Managing Director

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List of products, to which the above manufacturer's declaration applies:

Identification of the product (e.g., product name, family/group name device model or catalogue number)	**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**	**End date of extended validity/transition period**
10003279 NO-A EKU therapy unit	P20-00136-168088	2024-05-26	mdc medical device certification GmbH 0483	2028-12-31
10003326 NO-A EKU therapy unit including O2-measurement	P20-00136-168088	2024-05-26	mdc medical device certification GmbH 0483	2028-12-31
10002809 CARDINO therapy Unit	P20-00136-168088	2024-05-26	mdc medical device certification GmbH 0483	2028-12-31
10002426 flow measuring/ dosing module high-flow including connection cable, adapters, caps	P20-00136-168088	2024-05-26	mdc medical device certification GmbH 0483	2028-12-31
10002427 flow measuring/dosing module low-flow including connection cable, adapters, caps	P20-00136-168088	2024-05-26	mdc medical device certification GmbH 0483	2028-12-31
10003322 gas supply tube NO 1,5m stainless steel for NO-A and EZ-KINOX	P20-00136-168088	2024-05-26	mdc medical device certification GmbH 0483	2028-12-31

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10003329 gas supply tube NO 1,5m both-sided quick coupling Q-Series stainless steel for CARDINO	P20-00136-168088	2024-05-26	mdc medical device certification GmbH 0483	2028-12-31
10002460 gas input (dosing tube) for adult / paediatric use for NO-A, EZ-KINOX, CARDINO	P20-00136-168088	2024-05-26	mdc medical device certification GmbH 0483	2028-12-31
10003113 flow measuring module high-flow including connection cable & pull relief	P20-00136-168088	2024-05-26	mdc medical device certification GmbH 0483	2028-12-31
10003069 flow measuring module low-flow including connection cable & pull relief	P20-00136-168088	2024-05-26	mdc medical device certification GmbH 0483	2028-12-31
10003545 gas supply tube NO 1,0m stainless steel for NO-A and EZ-KINOX	P20-00136-168088	2024-05-26	mdc medical device certification GmbH 0483	2028-12-31
10003323 gas supply tube NO 3m stainless steel for NO-A and EZ-KINOX	P20-00136-168088	2024-05-26	mdc medical device certification GmbH 0483	2028-12-31
10003546 gas supply tube NO 3,0m both-sided quick coupling Q-series stainless steel	P20-00136-168088	2024-05-26	mdc medical device certification GmbH 0483	2028-12-31