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	E.M.S. Electro Medical Systems S.A.
Manufacturer address and contact details	Chemin de la Vuarpillière 31, 1260 Nyon, Switzerland +41 22 994 47 00
Single Registration Number (SRN) (if available)	CH-MF-000026136

Authorised Representative name (if applicable)	E.M.S. Electro Medical Systems FRANCE SARL
Authorised Representative address and contact details	32, Route de Pontarlier 39460 Foncine-Le-Haut France +33 3 84 51 90 01
Single Registration Number (SRN) (if available)	FR-AR-000011266

Notified body name (if applicable)	DEKRA Certification GmbH
Notified body number (if applicable)	0124
Directive Certificate number(s) to which this confirmation is made (if applicable)	50081-16-09

[1] The first condition is not applicable 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.

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Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	2024.05.26
End date of extended validity/transition period	2028.12.31

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) 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.

[2] The first condition is not applicable 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

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☐ 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.

☒ 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 (case of AIRFLOW Powders)**

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.

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Signed for and on behalf of the manufacturer: .

Full Company Name: E.M.S. Electro Medical Systems S.A.

Location & Date: Nyon, 29.04.2024

Signature, Print Name, Title:

Timothée Deblock
Head of Quality

Contact Details (at least email): ra-pcn@ems-ch.com

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E.M.S. ELECTRO MEDICAL SYSTEMS S.A.

Schedule of Devices

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

Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number) **BUDIDI Group name**	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
07613353001KQ LithoClast TRILOGY	50081-16-09	2024.05.26	DEKRA Certification GmbH 0124	DEKRA Certification GmbH 0124	2028.12.31	N/A
07613353008L6 LithoClast Master	50081-16-09	2024.05.26	DEKRA Certification GmbH 0124	DEKRA Certification GmbH 0124	2028.12.31	N/A
07613353013KX LithoClast 2	50081-16-09	2024.05.26	DEKRA Certification GmbH 0124	DEKRA Certification GmbH 0124	2028.12.31	N/A
07613353040L2 LITHO Handpieces	50081-16-09	2024.05.26	DEKRA Certification GmbH 0124	DEKRA Certification GmbH 0124	2028.12.31	N/A
07613353011KT LITHO Probes	50081-16-09	2024.05.26	DEKRA Certification GmbH 0124	DEKRA Certification GmbH 0124	2028.12.31	N/A
07613353048LJ LASER Fibers	50081-16-09	2024.05.26	DEKRA Certification GmbH 0124	DEKRA Certification GmbH 0124	2028.12.31	N/A

[3] for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number) **BUDIDI Group name**	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
07613353039LH Stone Catcher	50081-16-09	2024.05.26	DEKRA Certification GmbH 0124	DEKRA Certification GmbH 0124	2028.12.31	N/A
07613353051L7 Handpieces Suction Tubes	50081-16-09	2024.05.26	DEKRA Certification GmbH 0124	DEKRA Certification GmbH 0124	2028.12.31	N/A
07613353049LL Probes Suction Tubes	50081-16-09	2024.05.26	DEKRA Certification GmbH 0124	DEKRA Certification GmbH 0124	2028.12.31	N/A
07613353019LB LithoPump	50081-16-09	2024.05.26	DEKRA Certification GmbH 0124	DEKRA Certification GmbH 0124	2028.12.31	N/A
07613353002KS AIRFLOW Prophylaxis Master and AIRFLOW One	50081-16-09	2024.05.26	DEKRA Certification GmbH 0124	DEKRA Certification GmbH 0124	2028.12.31	N/A
07613353030KX PIEZON 250	50081-16-09	2024.05.26	DEKRA Certification GmbH 0124	DEKRA Certification GmbH 0124	2028.12.31	N/A
07613353028LC PIEZON Kits	50081-16-09	2024.05.26	DEKRA Certification GmbH 0124	DEKRA Certification GmbH 0124	2028.12.31	N/A
07613353033L5 AIRFLOW Handy 3.0	50081-16-09	2024.05.26	DEKRA Certification GmbH	DEKRA Certification GmbH	2028.12.31	N/A

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Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number) **BUDIDI** **Group name**	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
			0124	0124		
07613353021KW **PIEZON** **Handpieces**	50081-16-09	2024.05.26	DEKRA Certification GmbH 0124	DEKRA Certification GmbH 0124	2028.12.31	N/A
07613353016L5 **PERIOFLOW** **Handpieces**	50081-16-09	2024.05.26	DEKRA Certification GmbH 0124	DEKRA Certification GmbH 0124	2028.12.31	N/A
07613353035L9 **AIRFLOW** **Handpieces**	50081-16-09	2024.05.26	DEKRA Certification GmbH 0124	DEKRA Certification GmbH 0124	2028.12.31	N/A
07613353037LD **PIEZON** **Instruments**	50081-16-09	2024.05.26	DEKRA Certification GmbH 0124	DEKRA Certification GmbH 0124	2028.12.31	N/A
07613353036LB **PERIOFLOW** **Nozzles**	50081-16-09	2024.05.26	DEKRA Certification GmbH 0124	DEKRA Certification GmbH 0124	2028.12.31	N/A
07613353034L7 **Radial Shock Wave**	50081-16-09	2024.05.26	DEKRA Certification GmbH 0124	DEKRA Certification GmbH 0124	2028.12.31	N/A
07613353031KZ **DolorClast Master**	50081-16-09	2024.05.26	DEKRA Certification GmbH 0124	DEKRA Certification GmbH 0124	2028.12.31	N/A

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Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number) **BUDIDI Group name**	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
07613353026L8 DolorClast Smart 20	50081-16-09	2024.05.26	DEKRA Certification GmbH 0124	DEKRA Certification GmbH 0124	2028.12.31	N/A
07613353046LE DOLOR Handpieces	50081-16-09	2024.05.26	DEKRA Certification GmbH 0124	DEKRA Certification GmbH 0124	2028.12.31	N/A
07613353020KU AIRFLOW Powders	N/A, product up-classified under Regulation EU 2017/745			DEKRA Certification GmbH 0124	2028.12.31	N/A
07613353012KV DOLOR Applicators	50081-16-09	2024.05.26	DEKRA Certification GmbH 0124	Product down-classified as Class I under Regulation EU 2017/745		N/A

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Date 2020-12-17

Decision on the audit 1 / certification audit

Certification	**Regulation (EU) 2017/746 Annex IX Chapter I**

Dear Mr. Deblock

Based on audit report no. 50081-R1-00 it has been verified that your quality management system complies with the requirements.

Please note that a technical documentation must be positively verified before a certificate accorting to Regulation (EU) 2017/745 can be issued.

Notes

Basis of the continuing validity of the certificate is the regular performance of a yearly surveillance audit during the certificate's period of validity. The intention of the surveillance audit is the evaluation of the Quality management system's continued effectiveness according to the corresponding requirements.

Please note that your next audits are aligned with the already scheduled audits according to Directive 93/42EEC and EN ISO 13485:2016 and are to be carried out with the following periods:

audit 2 / 1st surveillance audit: between **2021-05-23 and 2021-08-23**
audit 3 / 2nd surveillance audit: between **2022-05-23 and 2022-08-23**

The prices for these audits will be included in a separate supplement to offer no. A20021254.

Yours sincerely

DEKRA Certification GmbH

Markus Kopf

DEKRA Certification GmbH • D-70565 Stuttgart, Handwerkstraße 15 •

Enclosures:

Audit Report No. 50081-R1-00 (sent electronically)
Invoice (sent electronically)