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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DEKRA Certification GmbH – Handwerkstraße 15 – D-70565 Stuttgart

E.M.S. Electro Medical Systems S.A.
Mr. Timothée Deblock
Chemin de la Vuarpillière 31
1260 Nyon
Switzerland

DEKRA Certification GmbH
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Contact Julia Scheu
Direct dial +49.711.7861-4158
Direct fax 49.711.7861-3450
Email julia.scheu@dekra.com

Headquarters
Tel. +49.711.7861-2566
Fax +49.711.7861-2615

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)

DEKRA Certification GmbH – Handwerkstraße 15 – D-70565 Stuttgart

E.M.S. Electro Medical Systems S.A.
Mr. Timothée Deblock
Ch. de la Vuarpillière 31
1260 Nyon
Switzerland

DEKRA Certification GmbH
Handwerkstraße 15
D-70565 Stuttgart

Headquarters
Phone +49.711.7861-2566
Fax +49.711.7861-2615

Date 2024-05-02

Subject: Notified Body Confirmation Letter

Our reference: 50081-CoL-00, Rev.0

Confirmation 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 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

Dear Mr. Deblock

This letter confirms that, DEKRA Certification GmbH, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0124 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:

E.M.S. Electro Medical Systems S.A.
Ch. de la Vuarpillière 31
1260 Nyon
Switzerland

SRN Number: CH-MF-000026136

The devices covered by the formal application and the written agreement mentioned above are identified in the Table provided in the Annex. This table identifies the devices for 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 MDD.

In the case of devices covered by certificates issued under 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 certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment

procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

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 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 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)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 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,

Digitally signed by Stephanie Donner
Date: 2024-05-02 16:23:49+02:00

Stephanie Donner
2024-05-02

Enclosures:

Confirmation Letter Annex

Annex to Notified Body Confirmation Letter 50954-CoL-00, Rev.0

Devices covered by this letter and for which the Notified body DEKRA Certification GmbH is also 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
07613353001KQ **LithoClast TRILOGY**	Class IIb excluding Class IIb implantable non-WET	N/A	**Certificate number:** Certificate 50081-16-09; dated: 2020-06-15 Annex Rev. 0, dated: 2020-06-15 **Notified Body:** DEKRA (0124)
07613353008L6 **LithoClast Master**	Class IIb excluding Class IIb implantable non-WET	N/A	**Certificate number:** Certificate 50081-16-09; dated: 2020-06-15 Annex Rev. 0, dated: 2020-06-15 **Notified Body:** DEKRA (0124)
07613353013KX **LithoClast 2**	Class IIb excluding Class IIb implantable non-WET	N/A	**Certificate number:** Certificate 50081-16-09; dated: 2020-06-15 Annex Rev. 0, dated: 2020-06-15 **Notified Body:** DEKRA (0124)
07613353040L2 **LITHO Handpieces**	Class IIb excluding Class IIb implantable non-WET	N/A	**Certificate number:** Certificate 50081-16-09; dated: 2020-06-15 Annex Rev. 0, dated: 2020-06-15 **Notified Body:** DEKRA (0124)
07613353011KT **LITHO Probes**	Class IIa	N/A	**Certificate number:** Certificate 50081-16-09; dated: 2020-06-15 Annex Rev. 0, dated: 2020-06-15 **Notified Body:**

			DEKRA (0124)
07613353048LJ **LASER Fibers**	Class IIa	N/A	**Certificate number:** Certificate 50081-16-09; dated: 2020-06-15 Annex Rev. 0, dated: 2020-06-15 **Notified Body:** DEKRA (0124)
07613353039LH **Stone Catcher**	Class I devices placed on the market in sterile condition	N/A	**Certificate number:** Certificate 50081-16-09; dated: 2020-06-15 Annex Rev. 0, dated: 2020-06-15 **Notified Body:** DEKRA (0124)
07613353051L7 **Handpieces Suction Tubes**	Class I devices placed on the market in sterile condition	N/A	**Certificate number:** Certificate 50081-16-09; dated: 2020-06-15 Annex Rev. 0, dated: 2020-06-15 **Notified Body:** DEKRA (0124)
07613353002KS **AIRFLOW Prophylaxis Master and AIRFLOW One**	Class IIa	N/A	**Certificate number:** Certificate 50081-16-09; dated: 2020-06-15 Annex Rev. 0, dated: 2020-06-15 **Notified Body:** DEKRA (0124)
07613353030KX **PIEZON 250**	Class IIa	N/A	**Certificate number:** Certificate 50081-16-09; dated: 2020-06-15 Annex Rev. 0, dated: 2020-06-15 **Notified Body:** DEKRA (0124)
07613353028LC **PIEZON Kits**	Class IIa	N/A	**Certificate number:** Certificate 50081-16-09; dated: 2020-06-15 Annex Rev. 0, dated: 2020-06-15 **Notified Body:** DEKRA (0124)

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
07613353033L5 **AIRFLOW Handy 3.0**	Class IIa	N/A	**Certificate number:** Certificate 50081-16-09; dated: 2020-06-15 Annex Rev. 0, dated: 2020-06-15 **Notified Body:** DEKRA (0124)
07613353021KW **PIEZON Handpieces**	Class IIa	N/A	**Certificate number:** Certificate 50081-16-09; dated: 2020-06-15 Annex Rev. 0, dated: 2020-06-15 **Notified Body:** DEKRA (0124)
07613353016L5 **PERIOFLOW Handpieces**	Class IIa	N/A	**Certificate number:** Certificate 50081-16-09; dated: 2020-06-15 Annex Rev. 0, dated: 2020-06-15 **Notified Body:** DEKRA (0124)
07613353035L9 **AIRFLOW Handpieces**	Class IIa	N/A	**Certificate number:** Certificate 50081-16-09; dated: 2020-06-15 Annex Rev. 0, dated: 2020-06-15 **Notified Body:** DEKRA (0124)
07613353037LD **PIEZON Instruments**	Class IIa	N/A	**Certificate number:** Certificate 50081-16-09; dated: 2020-06-15 Annex Rev. 0, dated: 2020-06-15 **Notified Body:** DEKRA (0124)

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
07613353036LB **PERIOFLOW Nozzles**	Class IIa	N/A	**Certificate number:** Certificate 50081-16-09; dated: 2020-06-15 Annex Rev. 0, dated: 2020-06-15 **Notified Body:** DEKRA (0124)
07613353034L7 **Radial Shock Wave**	Class IIa	N/A	**Certificate number:** Certificate 50081-16-09; dated: 2020-06-15 Annex Rev. 0, dated: 2020-06-15 **Notified Body:** DEKRA (0124)
07613353031KZ **DolorClast Master**	Class IIa	N/A	**Certificate number:** Certificate 50081-16-09; dated: 2020-06-15 Annex Rev. 0, dated: 2020-06-15 **Notified Body:** DEKRA (0124)
07613353026L8 **DolorClast Smart 20**	Class IIa	N/A	**Certificate number:** Certificate 50081-16-09; dated: 2020-06-15 Annex Rev. 0, dated: 2020-06-15 **Notified Body:** DEKRA (0124)
07613353046LE **DOLOR Handpieces**	Class IIa	N/A	**Certificate number:** Certificate 50081-16-09; dated: 2020-06-15 Annex Rev. 0, dated: 2020-06-15 **Notified Body:** DEKRA (0124)

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
07613353037LD **PIEZON Instruments**	Class IIa	N/A	**Certificate number:** Certificate 50081-16-09; dated: 2020-06-15 Annex Rev. 0, dated: 2020-06-15 **Notified Body:** DEKRA (0124)
07613353049LL **Probes Suction Tubes**	Class IIa	N/A	**Certificate number:** Certificate 50081-16-09; dated: 2020-06-15 Annex Rev. 0, dated: 2020-06-15 **Notified Body:** DEKRA (0124)
07613353019LB **LithoPump**	Class IIa	N/A	**Certificate number:** 50081-16-09 **Notified Body:** DEKRA (0124)

Nyon, March 12th, 2024

Letter of information

EMS MDR transition

Dear Valued Partner,

We,

E.M.S. Electro Medical Systems S.A.,
Chemin de la Vuarpillière 31,
1260 Nyon, Switzerland

Would like to inform you about the status of our transition to the new European Regulation 2017/745 on medical devices (MDR):

- In 2019, we opened an internal project to work on the transition;
- In 2020, we underwent a recertification audit according to the Directive 93/42/EEC on medical devices (MDD) to get a MDD CE Certificate valid until May 26th, 2024, date of the end of the initial transition period.
- In 2020, we underwent our first MDR audit and our Quality Management System (QMS) was considered as compliant with the MDR requirements by our notified body;
- Since 2020, we have several applications on-going with our notified body to get a MDR certificate covering all our medical devices;
- In 2021, all our Class I medical devices were considered as compliant with the MDR requirements and respective MDR declarations of conformity were signed.

Despite all these efforts, our MDD CE certificate will expire on May 26th, 2024, and all our medical devices won't be covered by a MDR CE certificate yet.

However, based on Article 1 of Regulation (EU) 2023/607, amending the MDR, our MDD CE certificate can still be considered as valid until December 31st, 2028, under certain conditions and we ensured to put everything in place to fulfill those specific conditions:

- Our medical devices continue to comply with Directive 93/42/EEC;
- There were no significant changes in the design and intended purpose of our medical devices;
- Our medical devices do not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health;
- We have put has put in place a quality management system in accordance with Article 10(9) of MDR before May 26th, 2024;

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- We have lodged formal applications with our notified body in accordance with Section 4.3, first subparagraph of Annex VII of MDR for conformity assessment before May 26th, 2024;
    - We will get a confirmation letter from our notified body stating that they have received our specific applications before May 26th, 2024;
    - We have prepared and signed a manufacturer's declaration stating that we have submitted those specific applications to our notified body;
- We will sign a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with our notified body before September 26th, 2024.

In this way, we will still be able to sell our medical devices until December 31st, 2028, even with an expired MDD CE Certificate.

Nevertheless, our objective is still to get a MDR CE Certificate for our main devices and related accessories below before the end of 2024:

- AIRFLOW Prophylaxis Master and AIRFLOW One;
- AIRFLOW Powders;
- Swiss LithoClast TRILOGY;
- Radial Shock Waves.

We remain at your disposal for further information.

Best regards,

Timothée Deblock
Head of Quality

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