Certification Agreement 50081-CA-00

Agreement covering the certification of a management system and devices(s) according to Regulation (EU) 2017/745 on medical devices

hereinafter "**Certification Agreement**"

Parties:

DEKRA Certification GmbH, having its seat in Stuttgart, Germany, hereinafter to be referred to as "DEKRA"

and

E.M.S. Electro Medical Systems S.A., having its seat in Nyon, Switzerland, hereinafter to be referred to as <Manufacturer>,

Whereas:

- DEKRA has been accredited by the German Accreditation Body for the assessment and certification of management systems (DAkkS),
- DEKRA has been designated as a Notified Body by the Competent Authority of Germany for Regulation (EU) 2017/745 (Medical Device Regulation)
- DEKRA shall perform an assessment of manufacturer's management system and/or device(s) to assess their compliance with the relevant standard(s) and Regulation, and
- DEKRA, should such an assessment lead to a positive result, shall be prepared to certify the manufacturer's management system and/or device(s) subject to the terms and conditions as specified below.

1) DEKRA is prepared to perform an assessment of the management system and/or assessment(s) of the conformity of the manufacturer's device(s) as listed in **Annex 1**.

2) DEKRA is prepared, such assessments lead to a positive result, to grant the right to use one or more certificates relevant to the fields of application specified in the certificate(s). In such a case DEKRA will issue one or more certificates to the manufacturer.

3) This Certification Agreement is based on the General Terms and Conditions, the General Certification Conditions and the Specific Certification Conditions (MDR/IVDR) of DEKRA Certification GmbH. The following hierarchy applies: Specific Certification Conditions (1); General Certification Conditions (2); General Terms and Conditions (3). The provisions in this agreement take precedence over the General Terms and Conditions and the General and Specific Certification Conditions.

4) The manufacturer hereby recognizes and agrees that any information provided by DEKRA to a regulatory authority in accordance with the General Terms and Conditions can be shared by such a regulatory authority with other relevant regulatory authorities.

5) The manufacturer shall pay certification fees, in accordance with the accepted quotation(s). Should the number of device certificates covered by this Certification Agreement will change, the certification fee will be adjusted accordingly.

6) DEKRA will issue quotations regarding the performance of a conformity assessment of a specific device or management system which are covered by this Certification Agreement. Should the manufacturer accept the quotation, the quotation will become a binding agreement between the Parties.

7) The manufacturer will lend its full co-operation to all assessments (audits and / or reviews) and inspections performed by DEKRA according to the relevant standards and requirements. Such audits, reviews and inspections shall be charged at the then applicable rates, unless the quotation contains a differing arrangement.

    a. The manufacturer shall allow DEKRA at any time proposed by the latter, at the frequency as specified in the quotation and in accordance with the applicable Standards, Directives, Regulations and other applicable EU regulatory documents, to investigate whether the management system and/or device(s) continue to be in compliance with the requirements. DEKRA shall notify the manufacturer in advance, except in the case of unannounced visits for the purpose as defined in the relevant Directives and/or Regulations.

8) The manufacturer shall promptly send DEKRA a copy of any and all vigilance reports sent by the manufacturer to the relevant Competent Authority.

9) Prior to expiry of each certificate's validity term DEKRA will conduct a renewal assessment. Such assessment shall be charged at the then applicable rates unless the quotation contains a differing arrangement. DEKRA issues quotations regarding the renewal of a conformity assessment of the specific device(s) or management system which are part of this Certification Agreement. Should the manufacturer accept the quotation, the quotation will become a binding agreement between the Parties.

10) This contract shall become effective as per the date specified above and shall be entered into for an indefinite time period. The agreement may be terminated by either party subject to three months' notice, up to the moment one or more certificates are issued. In these last cases each party shall have the right to give notice to terminate the Certification Agreement as of the expiry date of the current certificate's validity period. If the Certification Agreement covers more than one certificate, the agreement can be terminated with respect to each certificate as of the expiry date of the current validity period of the certificate in question. If substantial changes are made to the quality management system, or the device-range covered, Annex 1 of this Certification Agreement will be amended as necessary.

Signer accepts this Certification Agreement under the conditions listed above. Signer hereby orders DEKRA to execute the agreed services and declares that no other application for the device(s) listed in **Annex 1** have/has been lodged with any other Notified Body.

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We look forward to our successful cooperation.

DEKRA Certification GmbH
i.V. Markus Kopf
Director Medical Devices

Digital unterschrieben von Markus RAINER Kopf
Datum: 2024-09-23 08:43:19+02:00

Stuttgart, 2024-09-23

Client

E.M.S. Electro Medical Systems S.A.	Chemin de la Vuarpilliere 31, 1260 Nyon
Name of the company submitting the application	Address of the company submitting the application
Mr Timothée DEBLOCK Head of Quality	
Title, first name, last name of the client	
Nyon, Sept 24th, 2024	ELECTRO MEDICAL SYSTEMS SA Ch. de la Vuarpillière 31 CH-1260 NYON (Switzerland) Tél. +41 22 994 47 00 Fax +41 22 994 47 0
Place and Date (YYYY-MM-DD)	Legally binding signature of the client

Enclosures:
Annex 1 to Certification Agreement 50081-CA-00
General Terms and Conditions
General Certification Conditions
Specific Certification Conditions (MDR/IVDR)

Annex 1, Rev. 0 , to Certification Agreement 50081-CA-00

Device(s) for which an application according to Regulation (EU) 2017/745 (Medical Device Regulation) Article 52 have/has been lodged and for which the Notified Body DEKRA Certification GmbH will perform/has performed a conformity assessment in accordance with the applicable conformity assessment procedure in line with the submission date(s) given below:

Conformity assessment procedure according to Annex IX, Chapter I+III

☒ Class IIa:

Device name	Basic UDI-DI	Possible Date for submission of the technical documentation for review (YYYY-MM-DD))
LITHO Probes	07613353011KT	Already submitted
LASER Fibers	07613353048LJ	2025-12-31
AIRFLOW Prophylaxis Master and AIRFLOW One	07613353002KS	Already submitted
PIEZON 250	07613353030KX	2025-07-31
PIEZON Kits	07613353028LC	2025-07-31
AIRFLOW Handy 3.0	07613353033L5	2025-07-31
PIEZON Handpieces	07613353021KW	2024-10-31
PERIOFLOW Handpieces	07613353016L5	2024-10-31
AIRFLOW Handpieces	07613353035L9	2024-10-31
PIEZON Instruments	07613353037LD	2024-10-31
PERIOFLOW Nozzles	07613353036LB	2024-10-31
AIRFLOW Powders	07613353020KU	Already submitted
Radial Shock Wave	07613353034L7	Certified
DolorClast Master	07613353031KZ	2024-12-31
DolorClast Smart 20	07613353026L8	Ready to submit
DOLOR Handpieces	07613353046LE	Ready to submit
Probes Suction Tubes	07613353049LL	2025-12-31
LithoPump	07613353019LB	2025-12-31
Handpieces Suction Tubes	07613353051L7	2025-12-31

Annex 1, Rev. 0 , to Certification Agreement 50081-CA-00

☒ Class IIb[1]:

Device name	Basic UDI-DI	Possible Date for submission of the technical documentation for review (YYYY-MM-DD))
LithoClast TRILOGY	07613353001KQ	Already submitted
LithoClast Master	07613353008L6	2025-12-31
LithoClast 2	07613353013KX	2025-12-31
LITHO Handpieces	07613353040L2	Already submitted

☒ Class Is/Im/Ir:

Device name	Basic UDI-DI	Submission of the technical documentation for review (YYYY-MM-DD))
Stone Catcher	07613353039LH	Already submitted

Conformity assessment procedure according to Annex IX, Chapter I+II+III

☐ Class IIb[2]:

Device name	Basic UDI-DI	Submission of the technical documentation for review (YYYY-MM-DD))

☐ Class III:

Device name	Basic UDI-DI	Submission of the technical documentation for review (YYYY-MM-DD)

[1] Class IIb devices, other than custom-made or investigational devices, which are subject to a conformity assessment as specified in Chapter I and III of Annex IX, and including an assessment of the technical documentation as specified in Section 4 of that Annex of at least one representative device per generic device group (Article 52 MDR).
[2] Class IIb implantable devices, except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors (Article 52 MDR)

Annex 1, Rev. 0 , to Certification Agreement 50081-CA-00

Conformity assessment procedure according to Annex XI, Part A

☐ Class IIa:

Device name	Basic UDI-DI	Submission of the technical documentation for review (YYYY-MM-DD)

DEKRA Certification GmbH
i.V. Markus Kopf
Director Medical Devices

Digital unterschrieben von Markus RAINER Kopf
Datum: 2024-09-24 11:22:14+02:00

Stuttgart, 2024-09-23

Client

E.M.S. Electro Medical Systems S.A.	Chemin de la Vuarpilliére 31, 1260 Nyon
Name of the company submitting the application	Address of the company submitting the application
Mr Timothée DEBLOCK Head of Quality	
Title, first name, last name of the client	
Nyon, Sept. 24th, 2024	
Place and date (YYYY-MM-DD)	Legally binding signature of the client

EMS
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