DEKRA Certification GmbH – Handwerkstraße 15 – D-70565 Stuttgart

E.M.S. Electro Medical Systems S.A.
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Date 2024-10-07

Subject: Notified Body Confirmation Letter

Our reference: 50081-CoL-01 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 1 and Table 2 below.

Table 1 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.

Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the DEKRA Certification GmbH has not yet taken the responsibility 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issued under Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD certificate expiry; or provided evidence that a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)

Validity of this confirmation letter:

For products included in table 1 and table 2:

Until the end of applicable transition timelines specified in Article 120.3c of MDR (as amended by (EU) 2023/607)

On behalf of the Notified Body,

Digital unterschrieben von Markus RAINER Kopf
Datum: 2024-10-07 18:59:40+02:00

i.V. Markus Kopf
2024-10-07

Enclosures:

Confirmation Letter Annex

Annex to Notified Body Confirmation Letter 50081-CoL-01, Rev.0

Table 1

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 IIa	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	NA	**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)

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)
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)
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)

Table 2

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
07613353020KU **Airflow Powders**	Class IIa	07613353020KU Airflow Powders (Class I)	---