ANSM
French National Agency for
Medicines and Health Products Safety

FRENCH REPUBLIC

**DIVISION FOR MEDICAL DEVICES,
COSMETICS AND IN VITRO
DIAGNOSTIC DEVICES**

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**EUROS SAS
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France**

**Ms Carine ANGELI,
Director of Quality and Regulatory Affairs**

HERMES : 2201051/ N° OTES : 2023013000039

Saint Denis, January 30, 2023

Re : Request for non-opposition to the continuation of the placing on the market, by the manufacturer EUROS, medical devices not yet covered by EU/MDR certifications, until the delivery of these certifications by the notified body MDC (0483).

Dear Madam,

By letter dated January 18, 2023, you indicate to my services that 11 technical files of medical devices, of which the company EUROS is the legal manufacturer as holder of the CE marking, are in being reviewed by the notified body MDC (0483) as part of the EU certification process according to the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 relating to devices medical.
In this same letter, you specify that this process of certification of your files will probably not be finalized before the end of validity of the certificate no. CE 639319 of conformity with the directive 93/42/EEC which was issued to you by your former notified body BSI (2797), this certificate expiring on 12/02/2023.

Also, you are requesting my services for a transitional measure allowing EUROS to market these devices pending the finalization of their EU certification according to the aforementioned Regulation (MDR).

I remind you that Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 relating to medical devices came into effect on May 26, 2021.
Since that date, pursuant to its article 5, a device can only be placed on the market if it is in accordance with these Rules.
Pursuant to its article 52, the conformity assessment procedure for class III, IIb, IIa, and certain class I devices requires the prior intervention of a notified body.
Consequently, the transitional provisions provided for in Article 120 of this Regulation cannot continue beyond the expiry date of the certificates of conformity with Directive 93/42/EEC and your medical devices cannot therefore be on the market before obtaining their EU certification according to this Regulation.
Section 97.1 of the same Regulations provides that : *« Where, having performed an evaluation pursuant to Article 94, the competent authorities of a Member State find that a device does not comply with the requirements laid down in this Regulation but does 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, they shall require the relevant economic operator to bring the non-compliance concerned to an end within a reasonable period that is clearly defined and communicated to the economic operator and that is proportionate to the non- compliance. »*

In this context and in application of the above, you have transmitted to my services the following elements:

- List of the 11 technical files relating to the devices concerned by your request (in the form of an Excel table), with the status of progress with regard to the EU/MDR certification process and the corresponding provisional certification dates;
- Evidence of CE conformity certifications for all of these devices with Directive 93/42/EEC (MDD):
  - Certificate of conformity of the full quality assurance system no. CE 639319 issued by the notified body BSI (2797), valid until 12/02/2023;
  - Certificate of conformity of the design (Annex II.4 of the MDD) no. CE 667213 issued by the notified body BSI (2797), valid until 07/15/2023;
  - - Certificate of conformity of the design (Annex II.4 of the MDD) no. CE 667216 issued by the notified body BSI (2797), valid until 08/28/2023;
  - - Certificate of conformity of the full quality assurance system no. D1447900006 issued by the notified body MDC (0483), valid until 26/05/2024;
  - - Certificate of conformity of the design (Annex II.4 of the MDD) no. D1447900004 issued by the notified body MDC (0483), valid until 26/05/2024;
  - - Certificate of conformity of the design (Annex II.4 of the MDD) no. CE 667220 issued by the notified body BSI (2797), valid until 10/10/2023;
  - - Certificate of conformity of the full quality assurance system no. D1447900006 issued by the notified body MDC (0483), valid until 26/05/2024;
  - - Certificate of conformity of the design (Annex II.4 of the MDD) no. D1447900003 issued by the notified body MDC (0483), valid until 26/05/2024;
  - - Certificate of conformity of the design (Annex II.4 of the MDD) no. CE 667224 issued by the notified body BSI (2797), valid until 22/06/2023.
- Evidence that the EU certification procedures for compliance with Annex IX of Regulation (EU) 2017/745 have been initiated with your notified body MDC (0483) during the year 2022 on medical devices including the 11 technical files are listed in the appendix to your request (in the form of an Excel table), these proofs being as follows:
  - Contracts signed between EUROS and this notified body for the EU/MDR certification of these devices medical (11 contracts, i.e. one contract per technical documentation);
  - Confirmations of the offers transmitted in response by this notified body to EUROS, attesting to the admissibility of EU/MDR certification files (11 confirmation letters, i.e. one letter per technical documentation);
- EU certificate n° D1447900011 of EUROS QMS compliance with Annex IX Chapter I of the MDR issued by the notified body MDC (0483) on 25/07/2022, valid until 24/07/2026;
- Letter from EUROS dated 23/01/2023 certifying that:
  - This EU certificate of compliance of the QMS of EUROS with Annex IX Chapter I of the MDR will be revised after the EU certification of each technical documentation undergoing MDR certification, in order to gradually increase the devices concerned in the scope of this EU/MDR certificate of QMS compliance;
  - EUROS integrates into its quality management system the transitional provisions of article 120 of Regulation (EU) 2017/745 including in particular the requirements relating to post-marketing surveillance and materiovigilance since May 26, 2021, with regard to the devices concerned by this request ;
  - No significant change, within the meaning of MDCG 2020-3, has occurred since May 26, 2021 in the design or intended use of the devices concerned by this request;

- Review of materiovigilance incidents that have occurred over the last 3 years on the devices concerned by your request (integrated in the list provided in the form of an Excel table, regarding the 11 corresponding technical files).

Consequently, pursuant to Article 97 paragraph 1 of the aforementioned regulation, **the ANSM does not oppose, subject to conditions, the marketing of these medical devices for a period not exceeding April 30, 2023, in waiting for their compliance.**

The conditions for such marketing during the compliance period are as follows:

1. The absence of any event likely to call into question the safety of these devices, particularly in view of the vigilance data, as well as the maintenance of a favorable benefit/risk ratio for the use of these devices with regard to the the market surveillance data and the results of the audits carried out by the organization within the framework of the aforementioned certification procedures;
2. The absence of any substantial modification of these devices, with the exception of any corrective safety action implemented on the said devices, which you will please inform me of;
3. The obligation to inform your customers of the situation corresponding to this compliance period;
   In this respect, it is your responsibility to send this letter to your customers within 15 days, mentioning that this is a conditional agreement for a limited period of time;
4. The labelling of the devices concerned will not be changed and will bear the CE marking.

I would add, for information, that this decision applies to the territory of the European Union pursuant to guide MDCG 2022-18 published in December 2022, but does not prevent the competent authority of another Member State from taking measures that it deems justified, for its national market, addressed to other economic operator(s) concerned and relating to the devices covered by this document.

Finally, I remind you that it is your responsibility to comply with the applicable provisions relating to post-market surveillance and market surveillance for devices, as provided for in the Regulation.
In particular, any incident or risk of a serious incident defined in the first paragraph of Article 87 of this Regulation, which may result from the use of one of these devices, must be notified to me without delay.

In addition to the information requested above, I ask you to keep me regularly informed of the progress of the certification procedures undertaken with the notified body.

Please accept, Madam, the assurance of my highest consideration.

The deputy Director
Division for medical devices, Cosmetics
and In Vitro Diagnostic devices

Thierry THOMAS