1.7pd, 1.9pd

macopharma
DESIGNED FOR LIFE

Mouvaux, April 3rd, 2024

To whom it may concern,

Statement regarding the extended transitional period in accordance with the Regulation (EU) 2017/745 amended by the Regulation (EU) 2023/607.

MACO PHARMA's medical devices will benefit from the extended transitional period until December 31st, 2028 for class IIb, IIa, Is and Im medical device and until December 31st, 2027 for class III medical device.

As defined by the Regulation (EU) 2023/607, several conditions must be met to benefit from this extended transitional period.

We hereby certify that we have put in place a quality management system in accordance with the Regulation (EU) 2017/745 , this quality management system is certified by GMED to date and

- Complies with the Directive 93/42/EEC and the Regulation (EU) 2017/745 – Article 120 relating to post-market surveillance, market surveillance, vigilance, registration of economic operators and of devices;
- Have not been significantly change in the design and intended purpose;
- Do not pose an unacceptable risk to the health or safety of patients, users or other persons or to other aspects of the protection of public health;
- Is included in our application for MDR certification which is ongoing to obtain the updated contract and the confirmation letter from our notified body.

Best regards

Mounia NAJI
Regulatory Affairs Manager (Europe) – Clinical & Post-market surveillance