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emed
confidence in performance

Manufacturer
EMED SP. Z O. O. SP. K.
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Renewal of EC certificates

Legal basis:
Regulation (EU) 2023/607 of the European Parliament and of the Council of 15 March 2023 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

To whom it may concern,

in relation to the renewal of the transitional regulations on the basis of the amendments carried by Regulation (UE) 2023/607 in Article 120 of Regulation MDR (UE) 2017/745, we declare with full responsibility our readiness to meet the conditions for renewal of EC certificates in accordance with the MDD directive.

This means that **EC certificate** no TNP_MDD_0320_4919_2020 valid until 20th April 2023 issued by TUV NORD Poland no 2274 **remains valid until 31st December 2028** for all Class IIa and IIb products submitted for conformity assessment according to the requirements of the Regulation MDR (UE) 2017/745.

The MDD-compliant certificate renewal is automatic by law, which means that new certificates with extended expiration dates will not be issued by notified bodies.

The renewal does not apply to the declaration of conformity for Class I products manufactured by EMED. These products do not require to use of transition periods, these meet the requirements of Regulation MDR (UE) 2017/745 and are allowed to be traded or put into use on that basis.

We would like to inform you that as of 20th April 2023 Certificate for Quality Management System according to EN ISO 13485:2016 is no longer valid, as its renewal is not covered by Regulation (EU) 2023/607. The new EN ISO 13485:2016 certificate will be issued by TUV NORD Poland after a positive evaluation of the System is carried out simultaneously with the evaluation of the conformity of products with the requirements of Regulation MDR (UE) 2017/745. At the same time, we declare that we maintain and continuously update an effectively implemented QMS and post-market surveillance system. According to the requirements of MDR (EU) 2017/745, the manufacturer is not required to have a certified QMS.

Wioletta Nurczyk
Quality Manager, PRRC

2023.03.30