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**AKME**  
**Ms Anna Stachyra**  
**02-826 Warszawa. Ul. Poloneza 89B**  
**Warsaw**  
**Poland**

22<sup>nd</sup> March 2023

Dear Ms Anna Stachyra

You recently inquired about the Expiry Date as set out on the MDD CE certificate of conformity 669121 in the name of Smiths Medical for notably- our Ambulatory Infusion Pumps, Breathing, Bronchial Hygiene and Lung Expansion, Convective Warming, Fluid Warming, Humidification, Implantable Ports, Intubation, Pain Management, Pressure Monitoring, Sharps Safety, Subcutaneous Infusion Systems, Temperature Probes and Tracheostomy products.

A. Extension of the current transition period and CE Certificates

1. On 20 March 2023 the current transition period laid down in Article 120 of Regulation (EU) 2017/745 ('MDR') was extended by way of an Amendment to MDR.
2. As part of this, a parallel extension of the validity of certificates issued under the previous legislation Directive 93/42/EEC ('MDD') for all devices benefiting from such extended transition period, was also agreed.
3. This was done to ensure continued availability of medical devices on the market in light also of capacity shortages for conformity assessments by notified bodies.
4. Under this recent Amendment to MDR (as published in the Official Journal of the European Union on 20 March 2023 and with immediate 'entry into force'), the transition period (and the related certificates) was extended (i) until 31 December 2027 for higher risk devices respectively (ii) until 31 December 2028 for medium/lower risk devices.

Our relevant CE Cert was therefore *automatically* extended as contemplated by this Amendment to MDR. This extension of the transition period is then- as you likely know- subject to several cumulative conditions, which we currently expect to be able to meet.

B. Remediation efforts generally

ICU Medical have taken steps towards ensuring future compliance to MDR standards. One of these is that ICU Medical have already, i.e. prior to the moment of the expiry of the relevant CE Cert on 18 March 2023, signed a contract with our relevant notified body for the conformity assessment of the device(s) in question. ICU Medical have also taken other steps towards ensuring future compliance to MDR standards.

C. Additional clarifications:

1. For the avoidance of doubt, products that are on the shelves with you as a customer, are not impacted by the CE Cert expiry on 18 March 2023. This is because such products will have *already* been Placed on the Market prior to such CE Cert expiry i.e. irrespective of such CE Cert now having been extended.
2. Similarly, ICU Medical will continue to ship from such inventories that we currently hold in our EU-based warehouse because such products will have already been Placed on the Market prior to such CE Cert expiry i.e. irrespective of such CE Cert now having been extended.


D. Conclusion

In conclusion it is our current understanding that the relevant CE Cert was automatically extended and that therefore we are able to continue to Place on the market the relevant devices(s) also after the 18<sup>th</sup> of March 2023 and until further notice. We will therefore be able to continue to supply such products to you.

We trust that this letter takes away some of the concerns that you might have in this respect.

At the moment it is not expected that such CE Cert itself would be re-issued with a new date stated on it. This is also not needed, because the extension is automatic and by operation of law/MDR.

Kind regards,

DocuSigned by:  
  
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For Smiths Medical International Limited,

Louis Jones

Director