Advanced Medical Solutions Limited
Western Wood Way,
Langage Science Park,
Plymouth,
Devon,
PL7 5BG,
United Kingdom
Tel: +44 (0) 1752 209955 **Fax:** +44 (0) 1752 209956
Web: www.admedsol.com
Registered in England 2666957 VAT No. GB 636 5551 27

REF: Regulation (EU) 2023/607, amending Regulations (EU) 2017/745

Dear Valued Customer,

On the 20th March 2023, the European Union published Regulation (EU) 2023/607, amending Regulations (EU) 2017/745 (MDR) as regards the transitional provisions for certain medical devices to ensure a high level of public health protection, including patient safety and an avoidance of shortages of medical devices.

This amendment brings two significant changes to Article 120 of the MDR:

- Extending, under conditions, transitional periods for placing on the market or putting into service of legacy devices whose certificates under Directive 93/42/EEC (MDD) have already expired or are due to expire before 26 May 2024. This extension is immediately applicable, and Notified Bodies are not required to change the date on individual certificates.
- Abolishing the sell-off period set for May 26, 2025.

The certificate, CE 695793, of our medical device range expires in March 2024; we have verified the compliance of these devices with the conditions set out in the Amendment and we are pleased to inform you that the devices can be placed on the market under the Medical Device Directive until the dates listed below

- Laparoscopic Hernia Mesh Fixation : 31st December 2027.
- Open Hernia Mesh Fixation : 31st December 2027.
- Topical Wound Closure: Skin Closure System: 31st December 2028
- Topical Wound Closure: Topical Skin Adhesive: 31st December 2028
- Microbial Sealant: 31st December 2028

The following documents can be made available if required upon request, via your Advanced Medical Solutions contact or at RegsRequests@ademedsol.com :

- Self-declaration as per (EU) 2023/607 confirming that the conditions of the extension are fulfilled.
- Notified Body Letter confirming status of a formal application written agreement and appropriate surveillance in the framework of regulation (EU) 2O23/607 amending regulation (EU) 2O17/ 745 as regards the transitional provisions for certain medical devices.

Please note that we are progressing well towards approval of our entire range of these medical devices under MDR,

Thank you for communicating this letter to the concerned departments and we remain at your disposal if needed.

Yours Sincerely,

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James Bartlett
Regulatory and Clinical Director

16-Feb-24