



September 2, 2022

To: PELVITEC BV
Rotterdamseweg 183C
2629 HD DELFT
THE NETHERLANDS

From:

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Advance Medical Designs, Inc.
1241 Atlanta Industrial Drive
Marietta, GA 30066 USA

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Re: Notification of Voluntary Recall for AMD Needle Guides placed into the EU during 2020-2022 YTD.

This letter is meant to serve as notification to your company making you aware of a voluntary recall being conducted by Advance Medical Designs, Inc. regarding our sterile needle guides.

Explanation of Potential Hazard:

We were contacted by our Notified Body and informed that our needle guides listed below were deemed by the Notified Body to be outside the scope for the technical file they have been assigned to.

Product Subject to Recall:

<u>Part</u>	<u>lot#</u>	<u>Lot Qty</u>
28-TPG114	10129C1076	100 units
28-TPG114	10267C1106	2000 units
28-TPG114	220315C2173	370 units
28-TPG116	10165C083	30 units
28-TPH162	10430C1132	400 units
28-TPH162	10716C1190	250 units
28-TPH164	10689C1188	20 units
28-TPU166	10983C1242	40 units
28-TPU166	220256C2167	400 units

Further distribution or use of the above referenced products and lots should cease immediately. If your company has any of the above reference product and lots, please contact Advance Medical Designs, Inc. for an RGA number so that the product can be returned.

If you have any questions or concerns, or if you require further explanation of the issue at hand, please do not hesitate to contact me.

Regards,

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David Mackie
QA/RA Manager
Advance Medical Designs, Inc.
+1 (800) 221-3679
mackied@advmeddes.com