December 26, 2019

Information Letter about EU MDR

To All European Union Distributors,

Thank you for being a valued distributor of Cadwell Industries, Inc. We are pleased to inform you Cadwell is on track for compliance with the EU Medical Device Regulation (MDR) 2017/745 which becomes effective in May of 2020[1].

Cadwell's Notified Body, DEKRA Certification B.V. (CE 0344), recently received their designation under the EU MDR. DEKRA is scheduled to perform the first MDR audit of Cadwell's Quality Management System in the second half of 2020.

Cadwell is in the process of transitioning existing Cadwell MDD certified products to be CE certified under the MDR. During the transition period, MDD certified products can continue to be sold until the certificate expiration date. The current certificates can be found here: https://www.cadwell.com/about/.

If you have any questions regarding this letter, please contact Becky Corral at 509-735-6481 or quality@cadwell.com.

Sincerely,

BCorral

Becky Corral
QARA Manager
Cadwell Industries, Inc.

[1] Cadwell is ISO13485:2016 and MDSAP certified.