

May 22, 2023

Regarding:

CE Certification Extension

Product:

HyProCure® Sinus Tarsi Implant System

HyProCure® Sinus Tarsi Instrument Set

Manufacturer: Graham Medical Technologies, LLC dba GraMedica

16137 Leone Drive, Macomb, MI 48042 USA

To whom it may concern,

I am writing to update you on the status of MDD CE certification for our products being distributed to the European Union. We are transitioning and will obtain our MDR 2017/745 certification.

The European Parliament has amended the Medical Device Regulation 2017/745. We have met all of the conditions required and therefore, have been granted an automatic extension of our MDD certificate validity for our devices through 31 December 2028.

We believe it is important to maintain open communication, therefore, as soon as we are provided with a confirmation letter from our Notified Body's Global Team, we will forward it on to you.

Should you require any additional information, please do not hesitate to reach out to our sales team. Thank you for your continued patience and support.

Sincerely,

Tony Robinson
President & CEO

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