GRENA®

VAT no GB 821 2900 64

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Brentford 31.12.2020

To whom it may concern

STATEMENT

Regarding European regulations, manufacturers of medical devices from third countries (outside of the EU) shall appoint Authorized Representative. Information about Authorized Representative shall appear on labels and Instruction of Use for each medical device.

Grena Ltd., a manufacturer from the United Kingdom has appointed MDML INTL LTD. 10 McCurtain Hill, Clonakilty, Co. Cork, P85 K230, Republic of Ireland to be Authorized Representative. Such information will be added to the labels and IFU – as additional labels and leaflets until a new layout of packaging and the new revision of IFU will be implemented.

Sincerely,

Iwona Michalska

Quality Director