



ACE MEDICAL CO., LTD.
33 Naeyoo-road124,
Deogyang-gu, Goyang-si,
Gyeonggi-do, 10264,
Republic of Korea

Date: 20 February 2024

Confirmation Letter

To whom it may concern,

We hereby confirm that SGS Belgium NV, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 1639 on NANDO, has received a formal application from the following manufacturer, under the framework of (EU) 2017/745.

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10264, Gyeonggi-do
Republic of Korea
SRN Number: KR-MF-000022760

This letter confirms that the manufacturer's MDD certificate benefit from the extension period until 24 May 2024, provided the conditions set out in Article 120(3c), points (a) to (c), are fulfilled. Last MDD surveillance audit has been conducted by Ace medical Co Ltd in December 2023 leading to 3 minors Non conformities.

Please do not hesitate to contact us if you require any further information.

Yours sincerely,

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