



**LÆGEMIDDELSTYRELSEN**  
DANISH MEDICINES AGENCY

24. March 2021

To whom it may concern,

We, the Danish Medicines Agency, hereby confirm that

**Axelgaard Manufacturing Co.  
Møgelhøj 2  
8520 Lystrup  
Denmark  
CVR: 26868424**

is registered as an Authorized Representative in the European Union for the medical devices which are manufactured and CE-marked by

**Axelgaard Manufacturing Co., Ltd.  
520 Industrial Way  
Fallbrook, CA 82028  
United States of America**

Medical devices which are CE marked in conformity with Medical Device Regulation (MDR) (EU) 2017/745 meet the essential requirements for safety and performance. They may therefore be manufactured and marketed in Denmark and exported without any approval from the Danish Medicines Agency.

Kind regards,

**Lasse Lindvald Nielsen**  
Scientific Officer



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