

Medicines & Healthcare products Regulatory Agency

> 10 South Colonnade Canary Wharf London E14 4PU United Kingdom

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Advena Ltd Pure Offices Plato Close Warwick CV34 6WE England, United Kingdom

02 August 2021

Dear Jessica Ostle

We are pleased to confirm that the application to register or update an existing registration for the following manufacturer, which you submitted on 23 July 2021 has been reviewed:

Application reference: 2021072301209124

Manufacturer organisation: Anzai Medical Co., Ltd. Address: 3-9-15 Nishi-Shinagawa Shinagawa-ku Tokyo 141-0033 Japan

Manufacturer registration status: Registered

Device(s):

GMDN term	Status	MHRA comment
47928 - Accelerator system synchronizer	Registered	

Please note this letter does not represent any form of <u>accreditation</u>, <u>certification</u> or <u>approval</u> by the UK Competent Authority.

If you stop placing devices on the market or if you are not complying with the Regulations, you should inform us so that we can amend our records. You should be aware that it is an offence to place on the market UKCA or CE marked devices that do not comply with the regulations.

Please inform us of the following chargeable changes:

- 1. company/organisation information e.g. name and address
- 2. additional devices (GMDN code or term)

Please also use the Devices Online Registration Database (DORS) to tell us of the following changes e.g. removal/ discontinuation of a device (GMDN) or product from your registration record, change of contact person, telephone number and/or email address, for which payment of our statutory fee does not apply.

Please note that the name and address of manufacturer, UK Responsible Person or Authorised Representative (Northern Ireland only) and devices that have been registered will be published on our <u>Public Access Registration</u> <u>Database</u> (PARD).

The account number for your company/organisation is 0000016380.

Yours sincerely,

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Ngozi Onyeukwu Device registrations service Devices division MHRA