Medicines & Healthcare products
Regulatory Agency

EU MDR Article 120 extension confirmation

Manufacturer Name ('Manufacturer')	**Manufacturer Address**	**MHRA Account Number**
Avery Biomedical Devices, Inc.	61 Mall Drive, Commack, New York 11725 United States of America	13693
UKRP/Northern Ireland Authorised Representative Name (if applicable)	**UKRP/NI Authorised Representative Address**	**MHRA Account Number**
Advena Ltd	Pure Offices, Plato Close, Tachbrook Park, Warwick, CV34 6WE. UK	12309

I/we declare that:

- the CE certificate(s) listed below were issued under the EU Medical Devices Directive (93/42/EEC) or under the EU Active Implantable Medical Devices Directive (90/385/EEC) on or after 25 May 2017 and were still valid on 26 May 2021 **AND**

- the conditions for extension of the validity of the CE certificate(s) (under the EU Medical Devices Regulation (2017/745) (EU MDR) Article 120) set out below have been met in relation to the CE certificates as listed in the table below

[Complete the relevant table below]

	CE Certificate number/s	Notified Body that issued the CE certificate	Expiry date/s	Notified Body currently responsible for surveillance	Extended validity date(s) for NI market	Extended validity date(s) for GB market
a) That, in the case of a certificate that **expired before 20 March 2023** I/we/the manufacturer has a signed contract with a notified body that pre-dates the original expiry of the certificate		*Enter Name & Number*		*Enter Name & Number*		

	CE Certificate number/s	Notified Body that issued CE certificate	Expiry date/s	Derogation Reference Number & issuing Competent Authority (if any)	Notified Body currently responsible for surveillance	Extended validity date(s) for NI market	Extended validity date(s) for GB market
b) That, in the case of a certificate that **expired before 20 March 2023,** no such contract (set out in (a) above) was signed before the date of certificate expiry, and the Manufacturer was granted in respect of the device: - a derogation from the conformity assessment procedures under EU MDR Article 59 **OR** - a period of time to carry out conformity assessment in accordance with EU MDR Article 97		*Enter Name & Number*			*Enter Name & Number*		

	CE Certificate number/s	Notified Body that issued the certificate	Expiry date/s	Notified Body currently responsible for surveillance	Extended validity date(s) for NI market	Extended validity date(s) for GB market
c) The CE certificate(s) **was due to expire on or after 20 March 2023**, and remains valid by virtue of EU MDR Article 120(2).	CE 548726 CE 549647	BSI	May 26, 2024	BSI	December 31, 2028	June 30, 2028

Signed by Manufacturer:

Rommel Caguicla	**QA/RA Director**	**October 9, 2024**
Name of Signatory	**Position of Signatory**	**Date**

Signed by UK Responsible Person/Northern Ireland Authorised Representative (if applicable):

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Kirsty Ostle	**Managing Director**	**10th October 2024**
Name of Signatory	**Position of Signatory**	**Date**