

## Medicines & Healthcare products Regulatory Agency

## **EU MDR Article 120 extension confirmation**

Manufacturer Name	Manufacturer Address	MHRA Account Number
Penlon Limited	Abingdon Science Park, Barton Lane, Abingdon, Oxfordshire, OX14 3NB, United Kingdom	6844

## We declare that:

- the CE certificate listed below was issued under the EU Medical Devices Directive (93/42/EEC) on or after 25 May 2017 and was still valid on 26 May 2021 AND
- the conditions for extension of the validity of the CE certificate (under the EU Medical Devices Regulation (2017/745) (EU MDR) Article 120) set out below have been met in relation to the CE certificate as listed in the table below

	CE Certificate Details					
	CE Certificate number	Notified Body Number	Expiry date	Extended validity date for NI market	Extended validity date for GB market	
The CE certificate was due to expire on or after 20 March 2023, but remains valid by virtue of EU MDR Article 120(2).	GB20_965349	1639	13 Oct 2023	31 Dec 2028	30 Jun 2028	

Signed by:

Daniel Harrison (Name of Signatory)

QARA Manager (Position of Signatory)

18 July 2023 (Date)