



Medicines & Healthcare products Regulatory Agency

EU IVDR Article 110 extension confirmation (if you have not obtained a letter from your notified body)

Manufacturer Name ('Manufacturer')	Manufacturer Address	MHRA Account Number
NHSBT Reagents	14 Estuary Banks, Speke, Liverpool, L24 8RB	3237
UKRP/Northern Ireland Authorised Representative Name (if applicable)	UKRP/NI Authorised Representative Address	MHRA Account Number
N/A	N/A	N/A

I/we declare that:

- the CE certificate(s) listed below were issued under the EU In vitro diagnostic Devices Directive (98/79/EC) on or after 25 May 2017 and were still valid on 26 May 2022 **AND**
- the conditions for extension of the validity of the CE certificate(s) (under the EU In vitro diagnostic Devices Regulation (2017/746) (EU IVDR) Article 110) 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 9 July 2024 I/we/the manufacturer has a signed contract with a notified body that pre-dates the original expiry of the certificate		<i>Enter Name & Number</i>		<i>Enter Name & Number</i>		

	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 9 July 2024 , 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 IVDR Article 54(1) OR - a period of time to carry out conformity assessment in accordance with EU IVDR Article 92(1)		<i>Enter Name & Number</i>			<i>Enter Name & Number</i>		

	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 9 July 2024 , and remains valid by virtue of EU IVDR Article 110(2).	1434-IVDD-131/2022 1434-IVDD-131/2022 – Annex 1 1434-IVDD-132/2022	Polskie Centrum Badań i Certyfikacji SA (PCBC) 1434	27.05.2025	Polskie Centrum Badań i Certyfikacji SA (PCBC) 1434 An application has been made to transfer appropriate surveillance to BSI Group, The Netherlands B.V. 2797	31/12/2027	31/12/2027

Signed by Manufacturer:



Jeremy Kellington

Lead Quality Specialist

23/05/2025

Name of Signatory

Position of Signatory

Date

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

N/A

Name of Signatory

Position of Signatory

Date