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

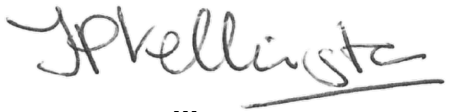
[Complete the relevant table below]

	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		*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 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)		*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 9 July 2024**, and remains valid by virtue of EU IVDR Article 110(2).	1433-IVDD-133/2022 1433-IVDD-133/2022 – Annex 1	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**