

## Letter of Explanation

05 July 2024

### To whom it may concern

We, Alba Bioscience Limited (under the parent company, AliveDx) at James Hamilton Way, Penicuik, EH26 0BF, hereby declare that we are both the Legal Manufacturer (LM) and Physical Manufacturer (PM) and endorse that the LM and PM are one and the same.

The products listed in **Annexure 1** and listed on the Certificate of Free Sale Number: 2022082202274584/1 dated 22/08/2022, (pertaining to distribution of products listed in said certificate in Vietnam).

MHRA state that if the LM and PM are one and the same, then only the Legal Manufacturer details are required to be listed on the Certificate of Free Sale.

Alba Bioscience Limited's (under the parent company, AliveDx) full postal address is:

Alba Bioscience Limited  
Allan-Robb Campus  
5 James Hamilton Way  
Milton Bridge  
Penicuik  
Scotland  
EH26 0BF  
United Kingdom

Some of the above details may be omitted on correspondence or issued documents, including but not limited to, the Certificate of Free Sale Number: 2022082202274584/1 dated 22/08/2022, without affecting the accuracy of the address. The details "Allan-Robb Campus", "5", "Milton Bridge" and "Scotland" are additional information, and not necessary to identify the Alba Bioscience Limited facility.

The minimum required to correctly identify the Alba Bioscience Limited facility in correspondence and issued documentation is:

Alba Bioscience Limited  
James Hamilton Way  
Penicuik  
EH26 0BF  
UK

We Alba Bioscience Limited, confirm that the product labelling and Instructions for Use will contain the ORTHO™ product codes listed in **Annexure 1**.

## Annexure 1

Medical Device Name	Product Code Alba / ORTHO
ORTHO™ Sera Anti-M	FD171B / 6904494
ORTHO™ Sera Anti-D (DVI)	FD039B / 6904623
ORTHO™ Sera Anti-D (IAT)	FD041B / 6904493
ORTHO™ Sera Anti-Fy <sup>a</sup>	FD151B / 6904486
ORTHO™ Sera Anti-Fy <sup>b</sup>	FD153B / 6904487
ORTHO™ Sera Anti-Jk <sup>a</sup>	FD162B / 6904488
ORTHO™ Sera Anti-Jk <sup>b</sup>	FD166B / 6904489
ORTHO™ Sera Anti-K	FD132B / 6904492
ORTHO™ Sera Anti-Le <sup>a</sup>	FD212B / 6904497
ORTHO™ Sera Anti-N	FD176B / 6904495
ORTHO™ Sera Anti-P1	FD202B / 6904496
ORTHO™ Sera Anti-s	FD186B / 6904491
ORTHO™ Sera Anti-S	FD182B / 6904490
ORTHO™ Sera Anti-Le <sup>b</sup>	FD217B / 6904498

Kind regards,



Janette Symonds  
Senior Regulatory Affairs Officer

**ALBA Bioscience Limited**  
5 James Hamilton Way  
Penicuik  
EH26 0BF  
United Kingdom