Medicines and Healthcare products Regulatory Agency

REGISTRATION OF MANUFACTURER, IMPORTER OR DISTRIBUTOR OF ACTIVE SUBSTANCES TO BE USED AS STARTING MATERIALS IN MEDICINAL PRODUCTS FOR HUMAN USE

Registrant Details

1. Registration Number	UK API 32930
2. Name or corporate name of registrant	SARTORIUS ALBUMEDIX LIMITED
3. Permanent or legal address of registrant	SARTORIUS ALBUMEDIX LIMITED, MABEL STREET, THE MEADOWS, NOTTINGHAM, NG2 3ED, UNITED KINGDOM
4. Address(es) of site(s) where registered activities take place	SARTORIUS ALBUMEDIX LIMITED, MABEL STREET, THE MEADOWS, NOTTINGHAM, NG2 3ED, UNITED KINGDOM
5. National legal basis of registration	Regulation 327 of The Human Medicines Regulations 2012 (SI 2012/1916)
6. Name of responsible officer of the competent authority of the member state validating the registration	Confidential
7. Date	09/03/2026

This registration form is valid only when presented with all pages. The authenticity of this registration form may be verified in MHRA-GMDP.

The registration holder referred to in section 2 shall communicate annually to the competent authority an inventory of the changes which have taken place as regards the information provided in this registration form. Any changes that may have an impact on the quality or safety of the listed active substances must be notified immediately.

SCOPE OF REGISTRATION

Name and address of the site

SARTORIUS ALBUMEDIX LIMITED, MABEL STREET, THE MEADOWS, NOTTINGHAM, NG2 3ED, UNITED KINGDOM

1. MANUFACTURING OPERATIONS

Active substance
RECOMBUMIN PRIME
4000014465

C	Manufacture of Active Substance using Biological Processes
	C.1 Fermentation
	C.3 Isolation / Purification

MHRA-GMDP

D	Manufacture of Sterile Active Substance
	D.1 Aseptically prepared
E	General Finishing Steps
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

RECOMBUMIN ELITE

4000015227

C	Manufacture of Active Substance using Biological Processes
	C.1 Fermentation
	C.3 Isolation / Purification
D	Manufacture of Sterile Active Substance
	D.1 Aseptically prepared
E	General Finishing Steps
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

2. IMPORTATION AND DISTRIBUTION OPERATIONS

B Distribution

RECOMBUMIN PRIME (4000014465)

RECOMBUMIN ELITE (4000015227)

MHRA-GMDP MHRA-GMDP MHRA MHRA