

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

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| 1. Registration Number | UK API 19819 |
| 2. Name or corporate name of registrant | BIOTEC SERVICES INTERNATIONAL LIMITED |
| 3. Permanent or legal address of registrant | BIOTEC SERVICES INTERNATIONAL LIMITED, BIOTEC HOUSE, CENTRAL PARK,
WESTERN AVENUE, BRIDGEND INDUSTRIAL ESTATE, BRIDGEND, CF31 3RT,
UNITED KINGDOM |
| 4. Address(es) of site(s) where registered
activities take place | BIOTEC SERVICES INTERNATIONAL LIMITED, UNITS 2100, 2110, 2120, 2130, 2010,
2430 AND 2500, PHASE 18, CENTRAL PARK, BRIDGEND INDUSTRIAL ESTATE,
BRIDGEND, CF31 3TY, 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 | 26/03/2024 |

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

BIOTEC SERVICES INTERNATIONAL LIMITED, UNITS 2100, 2110, 2120, 2130, 2010, 2430 AND 2500, PHASE 18, CENTRAL PARK, BRIDGEND INDUSTRIAL ESTATE, BRIDGEND, CF31 3TY, UNITED KINGDOM

2. IMPORTATION AND DISTRIBUTION OPERATIONS

- | | |
|---|-------------------------|
| B | Distribution |
| | RUSFERTIDE (3000023671) |
| | MK-3475 (3000017121) |