

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA(IMP) 29581
2: Name of authorisation holder	QUALASEPT LIMITED
3: Address(es) of manufacturing site(s)	QUALASEPT LIMITED, 3 CORSHAM SCIENCE PARK, PARK LANE, CORSHAM, SN13 9FU, UNITED KINGDOM
4: Legally registered address of authorisation holder	QUALASEPT LIMITED, 3 CORSHAM SCIENCE PARK, PARK LANE, CORSHAM, SN13 9FU, UNITED KINGDOM
5: Scope of authorisation and dosage forms	ANNEX 1 and/ or ANNEX 2
6: Legal Basis of authorisation	Part 6 of The Medicines for Human Use (Clinical Trials) Regulations 2004 [SI 2004/1031]
7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation	Confidential
8: Authorisation Date	26/02/2024
9: Annexes attached	Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

QUALASEPT LIMITED, 3 CORSHAM SCIENCE PARK, PARK LANE, CORSHAM, SN13 9FU, UNITED KINGDOM

Human Investigational Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)
Part 1 - MANUFACTURING OPERATIONS [1.1] Sterile Investigational Medicinal Products [1.1.1] Aseptically prepared (processing operations for the following dosage forms) [1.1.1.1] Large volume liquids [1.1.1.4] Small volume liquids [1.1.1.6] Other aseptically prepared products Penicillins, cephalosporins and cytotoxics, cytostatics [1.2] Non-sterile investigational medicinal products [1.2.1] Non-Sterile Products (processing operations for the following dosage forms) [1.2.1.5] Liquids for external use [1.2.1.6] Liquids for internal use

[1.5] Packaging

[1.5.1] Primary packaging

[1.5.1.5] Liquids for external use

[1.5.1.6] Liquids for internal use

[1.5.2] Secondary packaging

[1.6] Quality control testing

[1.6.2] Microbiological: non-sterility

[1.6.3] Chemical/Physical