

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA 8829

2: Name of authorisation holder CHIESI LIMITED

3: Address(es) of manufacturing site(s) CHIESI LIMITED, 333 STYAL ROAD,
MANCHESTER, M22 5LG, UNITED KINGDOM

4: Legally registered address of authorisation holder CHIESI LIMITED, 333 STYAL ROAD,
MANCHESTER, M22 5LG, UNITED KINGDOM

5: Scope of authorisation and dosage forms ANNEX 1 and/ or ANNEX 2

6: Legal Basis of authorisation Regulation 17 of The Human Medicines Regulations
2012 (SI 2012/1916)

**7: Name of responsible officer of the competent authority of the member
state granting the manufacturing authorisation** Confidential

8: Authorisation Date 21/11/2024

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

CHIESI LIMITED, 333 STYAL ROAD, MANCHESTER, M22 5LG, UNITED KINGDOM

Human Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)
Part 1 - MANUFACTURING OPERATIONS [1.2] Non-sterile products [1.2.2] Batch certification