Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number

2: Name of authorisation holder

3: Address(es) of manufacturing site(s)

4: Legally registered address of authorisation holder

5: Scope of authorisation and dosage forms

6: Legal Basis of authorisation

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

8: Authorisation Date

9: Annexes attached

UK MIA(IMP) 8829 CHIESI LIMITED

CHIESI LIMITED, 333 STYAL ROAD,

MANCHESTER, M22 5LG, UNITED KINGDOM

CHIESI LIMITED, 333 STYAL ROAD,

MANCHESTER, M22 5LG, UNITED KINGDOM

ANNEX 1 and/ or ANNEX 2

Part 6 of The Medicines for Human Use (Clinical

Trials) Regulations 2004 [SI 2004/1031]

Confidential

09/09/2024

Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

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

Human Investigational Medicinal Products

Authorised Operations

IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

[2.3] Other Importation Activities

[2.3.4] Other

Importation of QP certified IMPs from a country on the approved country for import list

Issue Date: 09 Sep 2024