Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA 37204

2: Name of authorisation holder CAST HEALTHCARE LIMITED

CAST HEALTHCARE LIMITED, UNIT E, THE BUSINESS CENTRE, 5-7

3: Address(es) of manufacturing site(s) TOBERMORE ROAD, DRAPERSTOWN, MAGHERAFELT, BT45 7AG,

UNITED KINGDOM

CAST HEALTHCARE LIMITED, UNIT E, THE BUSINESS CENTRE, 5-7

TOBERMORE ROAD, DRAPERSTOWN, MAGHERAFELT, BT45 7AG,

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

4: Legally registered address of authorisation holder

authority of the member state granting the

manufacturing authorisation

Confidential

8: Authorisation Date 02/10/2019

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

CAST HEALTHCARE LIMITED, UNIT E, THE BUSINESS CENTRE, 5-7 TOBERMORE ROAD, DRAPERSTOWN, MAGHERAFELT, BT45 7AG, UNITED KINGDOM

Human Medicinal Products

Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)

Part 1 - MANUFACTURING OPERATIONS

[1.5] Packaging

[1.5.2] Secondary packaging

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