Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA 4296

2: Name of authorisation holder B BRAUN MEDICAL LIMITED

B BRAUN MEDICAL LIMITED, UNIT 8, BROOKDALE ROAD,

3: Address(es) of manufacturing site(s) THORNCLIFFE PARK ESTATE, CHAPELTOWN, SHEFFIELD, S35

2PW, UNITED KINGDOM

B BRAUN MEDICAL LIMITED, UNIT 8, BROOKDALE ROAD,

4: Legally registered address of authorisation holder THORNCLIFFE PARK ESTATE, CHAPELTOWN, SHEFFIELD, S35

2PW, 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 05/11/2024

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

B BRAUN MEDICAL LIMITED, UNIT 8, BROOKDALE ROAD, THORNCLIFFE PARK ESTATE, CHAPELTOWN, SHEFFIELD, S35 2PW, UNITED KINGDOM

Human Medicinal Products

Authorised Operations

IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

[2.2] Batch certification of imported medicinal products

[2.2.1] Sterile Products

[2.2.1.2] Terminally sterilised

Issue Date: 05 Nov 2024